

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/18/2020 2:10:43 AM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fda]; Mark Eisner
 (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes
 | (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn | (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Bascles, Lionel | (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Michael
 (b) (6)]; Desrosiers, Betsy | (b) (6) |

CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
 (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Lucas Smalldon | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Kelly Beazley | (b) (6) Wung, Peter /US | (b) (6)

Subject: Follow-up to ACTIV TX-Clinical WG Master Protocol Subgroup - 2nd Meeting

Attachments: 2020-04-16_TX-Clinical_WG_Master_Protocols_Subgroup_Summary.pdf

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you all for your incredible help this week. I hope you all have a nice weekend and are able to get some rest!

Please find attached the final formal summary of our 2nd Subgroup call. Please review and let me know if you have any additions or amendments.

The co-chairs, subgroup chair, and I will be hard at work over the weekend on some materials. We look forward to sharing them with you all on Monday for our continued discussion. Please do not hesitate to reach out if you have any questions in the meantime!

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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Sent: 4/16/2020 12:49:19 PM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdiener, Keith | (b) (6) Hughes, Eric | (b) (6) Judy Carrier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Collis]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6)]; Jansen, Kathrin | (b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John | (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan | (b) (6)]; Tolman, Brett | (b) (6)]; Alvarez, Rosa | (b) (6) m]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Rose Li | (b) (6) Dana Carluccio | (b) (6)]; Rose Li Central Account [FN (b) (6) Anderson, Margaret | (b) (6) Lucas Smalldon | (b) (6)

Subject: ACTIV Therapeutics-Clinical Working Group Meeting #2
Attachments: ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 1_Key Takeaways_04152020v2.docx; ACTIVPrioritizationCriteria-v2.xlsx; 2020-04-14_TX-Clinical_WG_Agent_Prioritization_Subgroup_Summary.pdf; ACTIV Therapeutics-Clinical WG Meeting Agenda_04152020.pdf; ACTIV Therapeutics-Clinical WG 16Apr2020 Meeting Guide 04152020.pdf
Location: <https://zoom.us/> (b) (6)
Start: 4/16/2020 4:00:00 PM
End: 4/16/2020 5:30:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER)
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Rose Li; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smaldon

Dear COVID PPP Therapeutics-Clinical WG Members and Co-Chairs from other WGs,

Thank you all for all your hard work this week. We cannot thank you enough for your time and dedication to this important effort. Today's large group meeting will serve for the two subgroups to come back together and provide updates to each other and ensure we are staying on a unified path to move forward for this workstream.

Please find attached the materials for today's meeting:

1. Agenda
2. Slides for the presentation
3. Formal summary for Agent Prioritization Subgroup – 1st Meeting
4. Draft Agent Prioritization Criteria/Data Needed (Excel Sheet)
5. High Level summary and action items for the Master Protocol Subgroup – 1st Meeting

Note: The Master Protocol Subgroup will be having a second meeting immediately before this meeting, so we may be updating their summary slides on the fly during the meeting. Thank you for your patience and understanding with this fast moving process.

Reminder #1: If you are part of the Agent Prioritization Subgroup, we would like your feedback on the criteria in the Excel Spreadsheet attached.

Reminder #2: If you have not already done so, please fill out this Doodle Poll with your availability.

<https://doodle.com/poll/nhd5zgimn537aak5>

Agent Prioritization Subgroup we especially need you to fill out for tomorrow as soon as you can.

If you have any questions, please do not hesitate to reach out.

Kind regards,
Stacey, on Behalf of the TX-Clinical WG

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From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]
Sent: 9/9/2020 5:49:05 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Did you figure out how to make hover over work in a PDF?
The PPTX file is working fine.

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, September 9, 2020 1:45 PM
To: George, Jill (NIH/OD) [E] <(b) (6)> Brodd, Lauren (NIH/OD) [E] <(b) (6)>
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Hi Jill and Lauren,

The clinical trial matrix is out for review by the ACTIV Tx working group.

Jill -- Helen shared the attached PDF and I noticed the hover over does not work. I am not concerned about this issue given it's the WG reviewing but wanted to flag in case something needs to be tweaked in the PP file attached for future sharing using PDF.

Thanks,
Ashley

-----Original Message-----

From: Chen, Helen Q. <(b) (6)>
Sent: Wednesday, September 9, 2020 1:27 PM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>
Butterton, Joan <(b) (6)> De Claro, R. Angelo (FDA/CDER) <(b) (6)>
Drachia-Akli, Ruxandra <(b) (6)> Eisner, Mark <(b) (6)> Gottesdiener, Keith
<(b) (6)> Eric Hughes <(b) (6)> Judy Currier
<(b) (6)> Kim, Elizabeth <(b) (6)> LaVange, Lisa <(b) (6)>
Levy, Elliot <(b) (6)> Mellors, John W <(b) (6)> Menon, Sandeep
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Patel, Naimish
<(b) (6)> Peppercorn, Amanda <(b) (6)> Poole, Mike
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah
(NIH/NIAID) [E] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Shen, Yuan Li
(FDA/CDER) <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> .gov>: Wholley, David
(FNIH) [T] <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Collins, Sylva
(FDA/CDER) <(b) (6)> Amanda Peppercorn <(b) (6)> Garner, Carl
<(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Koroshetz, Walter
(NIH/NINDS) [E] <(b) (6)> Timothy Burgess <(b) (6)> Reineck, Lora
(NIH/NHLBI) [E] <(b) (6)> Adarwal, Neil (NIH/NHLBI) [E] <(b) (6)>
Rosenberg, Yves (NIH/NHLBI) [E] <(b) (6)> .gov>: Goff, David (NIH/NHLBI) [E]
<(b) (6)> Brown, Jeremy (NIH/NINDS) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Culp, Michelle (NIH/OD) [E] <michell (b) (6)> Jacqueline Kirchner
<(b) (6)> Beigel, John (NIH) [E] <(b) (6)> Phillips, L
Revell CIV DTRA RD (USA) <(b) (6)> Petrovick, Martha - 0449 - MITLL
<(b) (6)> Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael
(NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Young, John
<(b) (6)> Blass, Mary <(b) (6)> Butcher, Tina <(b) (6)>
<(b) (6)> Macone, Erin <erinm@amaon.com>: Melencio, Cheryl (FNIH) [T]
<(b) (6)> Salathin, Carla <(b) (6)> Tountas, Karen (FNIH) [T]
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Wachtel, Jonathan <(b) (6)> >: btolman <(b) (6)> Alvarez,
Rosa Maria <(b) (6)> Gonzalez, Nina <(b) (6)> Dana Carluccio
<(b) (6)> ; Rose Li Central Account <(b) (6)> Margaret
Anderson <(b) (6)> Lucas Smalldon <(b) (6)> Stratton,
Benjamin <(b) (6)> Mollica, Linda /US
<(b) (6)> Oashu, Felicia (NIH/OD) [E] <fel (b) (6)> Patterson, Amy
(NIH/NHLBI) [E] <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Marston,
Hilary (NIH/NIAID) [E] <(b) (6)> Wung, Peter /US <(b) (6)> Hoots, W. Keith
(NIH/NHLBI) [E] <(b) (6)> Groesch, Mary (NIH/NHLBI) [E] <(b) (6)> Shipp,

Allan (NIH/NHLBI) [E] < (b) (6) Kindzelski, Andrei (NIH/NHLBI) [E]
(b) (6) >; Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6) (<
Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) (b) (6) Freire, Maria (FNIH)
[T] < (b) (6) Elsaid, Olivia < (b) (6) Appell, Evan < (b) (6)
Subject: RE: ACTIV Therapeutics-Clinical Working Group Meeting

Dear ACTIV TX-Clinical Working Group Members,

As we have discussed previously, NIH has developed a table to summarize ACTIV and other NIH-supported COVID-19 trials. The goal of the table is to be informative to ACTIV and NIH leadership and to be shared more broadly once the information within it is public.

We would appreciate your review of this draft version of the table, which we are sharing ahead of tomorrow's Working Group meeting. Please do not share the table or the information in it further. We are looking forward to your input.

Warm regards,
Stacey, Mike, and Helen

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] < (b) (6)
Sent: Wednesday, June 17, 2020 8:48 AM
To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John W; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Prosch, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E]; Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beidel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6) Sizemore, Christine (NIH/FIC) [E]
Cc: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa Maria; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6); Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Freire, Maria (FNIH) [T]; Elsaid, Olivia
Subject: ACTIV Therapeutics-Clinical Working Group Meeting
When: Thursday, September 10, 2020 1:00 PM-2:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us> (b) (6)

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APAR0000002235-2517407

Sent: 7/1/2020 3:05:14 AM
Subject: FW: Materials for July 1 ACTIV Partnership Leadership Call
Attachments: ACTIV Leadership Team Meeting 20200630 FINAL.pptx; 2020-06-03_ACTIV_Leadership_Group_Meeting_Summary Final.docx; Zoom instructions for July 1 2020 call final_.docx

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, June 30, 2020 10:43 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco <(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lee, William <(b) (6)> Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene <(b) (6)> Pao, William <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)> Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni <(b) (6)> Rasi, Guido <(b) (6)> Reed, John <(b) (6)> Reese, David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky, Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael <(b) (6)> Tsai, John <(b) (6)> Vessey, Rupert <(b) (6)> Virgin, Skip <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Young, John <(b) (6)> : Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Castillejos, Carlos <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Hughes, Eric <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)> Mallory, Raburn <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Alvarez, Rosa <(b) (6)> Anderson, Margaret <(b) (6)> Chen, Helen <(b) (6)> oelsaid <(b) (6)> Gonzalez, Nina <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Ben <(b) (6)> Tolman, Brett <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Gorman, Greta (FNIH) [T] <(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Villafana, Tonya

Subject: Materials for July 1 ACTIV Partnership Leadership Call

Dear Colleagues:

Thank you very much for taking time to join Francis Collins, Paul Stoffels, and the rest of our Executive Committee tomorrow, July 1, from 1:00 p.m. – 2:30 p.m. Eastern U.S. time to discuss the progress of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership since our last call on June 3. You should have received a calendar invitation for the teleconference, which FNIH will be hosting. Please contact Cheryl Melencio and Joe Menetski at FNIH if you have any issues preparing for or signing into Zoom for the teleconference ((b) (6) or (b) (6)).

Attached you will find the following materials for the meeting:

- 1) The PowerPoint slide deck for the meeting, which includes the meeting agenda
- 2) The meeting minutes from our June 3 meeting (previously sent to you on June 4)
- 3) Instructions on how to use the Zoom app to access and participate in the meeting.

We look forward to speaking with you tomorrow and hearing your feedback.

Join Zoom Meeting

<https://fnih.zoom>. (b) (6)

Dial by your location

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US (New York)
US (San Jose)
US (San Jose)
US (Tacoma)
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Meeting ID: (b) (6)

Password: (b) (6)

Password: (b) (6)

Regards,

David Wholley

Senior Vice President, Research Partnerships

Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAFE06EBD70-PARKERAS]
Sent: 8/28/2020 2:27:04 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thanks! The vaccines and CT capacity WG are done but I will move the checks!

From: George, Jill (NIH/OD) [E] <(b) (6)>
Sent: Friday, August 28, 2020 9:45 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thanks for converting! Pretty soon you won't need me at all! 😊
Move the animated the checks as needed. Made a logical assumption, but could be wrong!
Jill

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Friday, August 28, 2020 9:15 AM
To: George, Jill (NIH/OD) [E] <(b) (6)>
Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

I converted them PP.

From: George, Jill (NIH/OD) [E] <(b) (6)>
Sent: Friday, August 28, 2020 9:12 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Darn. These are all PDFs. Any PPTX files?

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Friday, August 28, 2020 8:49 AM
To: George, Jill (NIH/OD) [E] <(b) (6)>
Subject: FW: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Importance: High

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, August 25, 2020 9:47 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)>; Bancel, Stephane
<(b) (6)>; Carter, Kara <(b) (6)>; Cavaleri, Marco
<(b) (6)>; Cihlar, Tomas <(b) (6)>; Collins, Francis (NIH/OD) [E]
<(b) (6)>; Corey, Larry <(b) (6)>; Culp, Michelle (NIH/OD) [E] <(b) (6)>;
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)>; Dolsten, Mikael <(b) (6)>; Erbeling,
Emily (NIH/NIAID) [E] <(b) (6)>; Erck, Stan <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E]
<(b) (6)>; Freire, Maria (FNIH) [T] <(b) (6)>; Gadbois, Ellen (NIH/OD) [E]
<(b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Hudson, Thomas

(b) (6) >; James, Stephanie (FNIH) [T] < (b) (6) Johnson, Robert (OS/ASPR/BARDA)
 < (b) (6) Kramer, Lynn < (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6)
 Lepore, John (b) (6) >; Marks, Peter (FDA/CBER) (b) (6) >; Marston, Hilary
 (NIH/NIAID) [E] (b) (6) ; Mascola, John (NIH/VRC) [E] (b) (6) >; Meeker, David
 < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Messonnier, Nancy
 (CDC/DDID/NCIRD/OD) (b) (6) ; Pandya, Hitesh < (b) (6) >; Pangalos, Mene
 (b) (6) ; Pao, William < (b) (6) ; Parker, Ashley (NIH/OD) [E]
 < (b) (6) Paul, Steve < (b) (6) ; Perlmutter, Roger (b) (6) ;
 Plenge, Robert < (b) (6) Plump, Andy < (b) (6) Rachel Ramoni
 (b) (6) Rasi, Guido < (b) (6) ; Reed, John (b) (6) ; Reese, David
 < (b) (6) Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] (b) (6) Skovronsky,
 Daniel (b) (6) Stein, Peter (FDA/CDER) (b) (6) >; Stoffels, Paul
 (b) (6) Tabak, Lawrence (NIH/OD) [E] (b) (6) >; Talley, Michael
 < (b) (6) ; Tsai, John < (b) (6) ; Vessey, Rupert (b) (6) ; Virgin, Skip
 < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Woodcock, Janet (FDA/CDER)
 (b) (6) Young, John (b) (6) Colvis, Christine (NIH/NCATS) [E]
 (b) (6) ; Desrosiers, Betsy (b) (6) ; Eric Hughes
 < (b) (6) ; Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]
 (b) (6) ; Lowy, Douglas (NCI) (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) ;
 Young, John < (b) (6)
 Cc: Adam, Stacey (FNIH) [T] < (b) (6) Alvarez, Rosa (b) (6) >; Anderson, Margaret
 (b) (6) Chen, Helen (b) (6) >; Elsaid, Olivia (b) (6)
 Gonzalez, Nina (b) (6) >; Hawk, Harrison < (b) (6) Menetski, Joseph (FNIH) [T]
 < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Stratton, Benjamin < (b) (6) ;
 btolman (b) (6) ; Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan
 (b) (6) >; Wholley, David (FNIH) [T] (b) (6) Anderson, James (NIH/OD) [E]
 < (b) (6) >; Austin, Christopher (NIH/NCATS) [E] (b) (6) Burklow, John (NIH/OD) [E]
 < (b) (6) Castillejos, Carlos < (b) (6) ; Culp, Michelle (NIH/OD) [E]
 (b) (6) FNIH Central Account (b) (6) ; Freire, Maria (FNIH) [T]
 (b) (6) ; Gadbois, Ellen (NIH/OD) [E] < (b) (6) >; Hallett, Adrienne (NIH/OD) [E]
 (b) (6) ; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Myles, Renate (NIH/OD) [E]
 < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E]
 (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] (b) (6) >; Burklow, John (NIH/OD) [E]
 < (b) (6) Gorman, Greta (FNIH) [T] (b) (6) ; Hallett, Adrienne (NIH/OD) [E]
 (b) (6) ; Meltzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E]
 (b) (6) Wolinetz, Carrie (NIH/OD) [E] (b) (6) >; Lucas Smalldon
 (b) (6) >; Villafana, Tonya (b) (6) >; Brian Rosen
 (b) (6)

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

Join Zoom Meeting

<https://nih.zoom.us>

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Meeting ID: (b) (6)

Passcode: (b) (6)

One tap mobile

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US (Chicago)

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Meeting ID: 544 281 8826

Passcode: 150160

Find your local number: <https://fnih.zoom.us> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/10/2020 2:54:23 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: Other Companies to give a heads up

Suggestions as to the message to convey? Are we open to adding other members to the WGs?

FC

From: Wholley, David (FNIH) [T] < > (b) (6)
Sent: Friday, April 10, 2020 10:40 AM
To: Collins, Francis (NIH/OD) [E] < > (b) (6)
Cc: Menetski, Joseph (FNIH) [T] < > (b) (6) Wood, Gretchen (NIH/OD) [E] < > (b) (6)
Subject: FW: Other Companies to give a heads up

Francis, here are the major folks to reach out to (thanks to Joe Menetski for this):

Regeneron - George Yancopoulos (b) (6)
Gilead - William Lee (b) (6)
Eisai - Lynn Kramer (was on Rupert Vessey's list of folks to include on TX list but we did not have room). He's VP, Chief Clinical Officer, Neurology Business Group (b) (6)
Biogen - Al Sandrock (b) (6)
Abbvie - Tom Hudson (b) (6)
Lilly - Dan Skovronsky (b) (6)
George Scangos (now at Vir) (b) (6)
Amgen - David Reese (you can thank him for participation of Elliott Levy (SVP Global Devt) on the TX-Therapeutics WG. He is part of the Vessey/Plump group but worth reaching out to directly—and a great partnership person, by the way) (b) (6)

Addit ons: Perhaps Stephane Bancel at Moderna, given the partnership with NIH? I have also not included anyone from Boehringer-Ingelheim or Bayer. Shall we try to get you those names and email addresses?

David

From: Santos, Michael (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 5/18/2020 7:22:02 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd];
(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell
(b) (6) [(b) (6) [(b) (6) [(b) (6) [(b) (6) Cavaleri Marco
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Greg Glenn [(b) (6) (b) (6) (b) (6) Haynes,
Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002 mc]; (b) (6)
(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John
(NIH/VR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy
(CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56fdb4e598a57b423d484dcf9f-offit.email]; HSchuite@ts.jnj.com;
Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan Se];
(b) (6) Tal Zaks [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen
(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];
(b) (6) Jeneffer Haynes [(b) (6) [(b) (6)
(b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj];
(b) (6) Isabel Ramsey [(b) (6) Parker, Ashley (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboiset]; Wholley, David (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
 [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
 (b) (6) Paul Gillard [(b) (6) Hamilton, Holli (OS/ASPR/BARDA)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli Hamil]; Modjarrad, Kayvon CIV
 USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som];
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Wachtel, Jonathan (b) (6) Stratton, Benjamin [(b) (6) Anderson, Margaret
 [marga (b) (6) rose. (b) (6) dana.carl (b) (6) Bethany Stokes
 [(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]

Subject: Canceled: ACTIV Vaccines Working Group meeting
Location: Webex: <https://nih.webex> (b) (6)

Start: 6/9/2020 4:00:00 AM
End: 6/10/2020 4:00:00 AM
Show Time As: Free

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
 (b) (6) Cavaleri Marco; (b) (6)
 (b) (6) Greg Glenn; (b) (6) Haynes,
 Barton; (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
 Messonnier, Nancy (CDC/DDID/NCIRD/OD); Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA); Offit, Paul;
 (b) (6) Seals, Jonathan (OS/ASPR/BARDA); (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay, Kozlowsk, Mary (NIH/NCI) [C]; Johnson, Maureen
 (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
 (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
 Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
 Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
 Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
 Desrosiers, Betsy, Hughes, Eric, Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
 Gillard, Hamilton, Holli (OS/ASPR/BARDA), Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
 (b) (6) (b) (6) Bethany Stokes; Ann Arvin

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/4/2020 9:19:15 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan (b) (6)]; Collins, Sylva (FDA/CDER) (b) (6) De Claro, R. Angelo (FDA/CDER) | (b) (6) Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Amanda Peppercorn | (b) (6) Price, Dionne (FDA/CDER) | (b) (6) Rubin, Daniel B. (FDA/CDER) | (b) (6) Shen, Yuan Li (FDA/CDER) | (b) (6) Farley, John (FDA/CDER) (b) (6)]; Goff, David (NIH/NHLBI) [E] | (b) (6)]; Vincent, Michael | (b) (6) Wung, Peter /US | (b) (6) Karen Lynn Price | (b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] | (b) (6)]; Patterson, Amy (NIH/NHLBI) [E] | (b) (6) Judy Currier (b) (6) Pamela Tenaerts, M.D. | (b) (6)
CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6) Wachtel, Jonathan (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] | (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] | (b) (6) |

Subject: ACTIV TX-C inical Master Protocol Ad Hoc Meeting
Location: <https://fnih.zoom.us/j/9181111111> (b) (6)

Start: 5/5/2020 6:00:00 PM
End: 5/5/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson, Collins, Sylva (FDA/CDER), Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn, Proschan, Michael (NIH/NIAID) [E], Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]; Patterson, Amy (NIH/NHLBI) [E]
Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan, Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Hoots, W. Keith (NIH/NHLBI) [E]

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
<https://fnih.zoom.us/j/9181111111> (b) (6)

Meeting ID: (b) (6)
Password: (b) (6)
One tap mobile (b) (6)

US (New York)
US (Germantown)

Dial by your location

(b) (6)

US (New York)

US (Germantown)

US (Chicago)

US (Houston)

US (San Jose)

US (San Jose)

US (Tacoma)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/19/2020 8:39:51 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdener, Keith (b) (6) Hughes, Eric | (b) (6) Judy Currier
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6)
CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Time Sensitive Request for Response from ACTIV Therapeutics-Clinical Working Group

Dear ACTIV Therapeutics-Clinical Working Group Members,

I hope this message finds you well. I am writing to seek your approval to publicly list your name in association with this ACTIV working group. A reporter has reached out to the FNIH asking for the names of the working group members, and we would like to point them to a listing of these names on the FNIH website, once you have provided clearance for this.

The FNIH's Vice President of Communications and Events, Abbey Meltzer, will be tracking these approvals, so please send your approval to her at (b) (6). If you have any questions, please do not hesitate to reach out to Abbey.

Best,
Stacey

Stacey J. Adam, PhD

APAR0000023373-2517414

Director, Cancer
Research Partnerships

Foundation for the National Institutes of Health

Direct: (b) (6) | Mobile: (b) (6)

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/20/2020 1:54:12 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Re: Clinical Trial Capacity WG - meeting #1 summary
Attachments: Master and WG Email List for ACTIV rv 042020.xlsx

Good morning Cheryl,

The attached list has Robert Johnson added to the master list and Rick Bright is removed. I standby on adding him to the WG's until we hear back from Francis.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Monday, April 20, 2020 9:27 AM
To: Melencio, Cheryl (FNIH) [T] <(b) (6)> Gonzalez, Nina <(b) (6)> Stratton, Benjamin <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)>
Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Can we please send an invitation to Robert Johnson to attend the Wednesday ACTIV leadership group call? He will likely be replacing Rick Bright on that call, but we won't know for sure until Francis Collins has had a few more conversations.

From: Johnson, Robert (OS/ASPR/BARDA) <(b) (6)>
Sent: Monday, April 20, 2020 7:04 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Tountas, Karen (FNIH) [T] Walker, Robert (OS/ASPR/BARDA) <(b) (6)>
Subject: RE: Clinical Trial Capacity WG - meeting #1 summary

David,

Hi and thanks for the follow-up. your assessment aligns with mine-so it's okay if we remove Jim from the list of participants for this WG?

Thanks.

Robert

Robert Johnson, Ph.D.
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: (b) (6)

Cell: (b) (6)
email: (b) (6)

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From: Wholley, David (FNIH) [T] < (b) (6) >
Sent: Sunday, April 19, 2020 7:12 AM
To: Johnson, Robert (OS/ASPR/BARDA) < (b) (6) >
Cc: Tountas, Karen (FNIH) [T] < (b) (6) >
Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Hi Robert, Karen Tountas forwarded me your note below. Francis Collins asked Rick Bright for names for three of the groups—Clinical TX, Predinical TX, and Vaccines. There was no request for a BARDA representative for the Clinical Trial Capacity group that I'm aware of, although if BARDA wanted to add one I'm sure there would be no objection.
David Wholley

From: Johnson, Robert (OS/ASPR/BARDA) < (b) (6) >
Sent: Sunday, April 19, 2020 6:55 AM
To: Tountas, Karen (FNIH) [T] < (b) (6) >
Cc: Walker, Robert (OS/ASPR/BARDA) < (b) (6) >; King, James (OS/ASPR/BARDA) < (b) (6) >; Johnson, Robert (OS/ASPR/BARDA) < (b) (6) >
Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

Karen,

Good morning. My name is Robert Johnson and I serve as the IMT manager for the COVID-19 response in BARDA. I'm trying to sort something out and hope you can help. Last weekend BARDA was asked to provide names of individuals to sit on three of the four PPP WGs. We were not asked to provide a name for the fourth working group, Clinical Trial Capacity, so we did not put one forth. I am not sure how Dr. King's name was added to the roster. Can you please clarify if BARDA is being requested to add someone to this WG? If so, we'll circle back with a name.

Thank you.

Robert

Robert Johnson, Ph.D.
Director, Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: (b) (6)
Cell: (b) (6)
email: (b) (6)

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From: King, James (OS/ASPR/BARDA) (b) (6)
Sent: Friday, April 17, 2020 8:21 AM
To: Johnson, Robert (OS/ASPR/BARDA) <(b) (6)>
Subject: FW: Clinical Trial Capacity WG - meeting #1 summary

I will send this to you and I will call

Jim King

From: Tountas, Karen (FNIH) [T] (b) (6)
Sent: Thursday, April 16, 2020 11:46 AM
To: Bascles, Lionel <(b) (6)> Cohen, Myron (b) (6) >; Corey, Larry
<(b) (6)> Desrosiers, Betsy (b) (6) Dickens, Jim (NIH/NCATS) [C]
<(b) (6)> ; Doroshow, James (NIH/NCI) [E] (b) (6) >; Goff, David (NIH/NHLBI) [E]
<(b) (6)> King, James (OS/ASPR/BARDA) <(b) (6)> . Kurilla, Michael (NIH/NIAID) [E]
<(b) (6)> Nayak, Seema (NIH/NIAID) [E] <(b) (6)> Parker, Ashley (NIH/NCI) [F]
<(b) (6)> ; Payton, Manizhe (NIH/NIAID) [E] (b) (6) >; Resnansky, Laura
<(b) (6)> Srinivasan, Badhri <(b) (6)> Stein, Peter (FDA/CDER)
<(b) (6)> Vincent, Mike (b) (6) ; Woodcock, Janet (FDA/CDER)
(b) (6)
Cc: Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Hughes, Eric (b) (6) ; Jansen, Kathrin
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E]
(b) (6) Young, John (b) (6) ; Criffield, Robin (b) (6)
Hamilton, Nancy (b) (6) Melencio, Cheryl (FNIH) [T] <(b) (6)> Minnich, Beth
<(b) (6)> Katz, Rebecca (NIH/NCATS) [E] <(b) (6)> Thomas, Ashley (FDA/CDER)
(b) (6) ; Adam, Stacey (FNIH) [T] (b) (6) >; Anderson, Margaret
>; Carluccio, Dana <(b) (6)> Melencio, Cheryl (FNIH) [T]
<(b) (6)> Gonzalez, Nina (b) (6) Heaton, Penny <(b) (6)>
James, Stephanie (FNIH) [T] (b) (6) ; Li, Rose (b) (6) ; Menetski, Joseph (FNIH) [T]
(b) (6) >; Santos, Michael (FNIH) [T] (b) (6) >; Tuveson, Nancy
(b) (6) ; Wholley, David (FNIH) [T] (b) (6) ; Wachtel, Jonathan
(b) (6)
Subject: RE: Clinical Trial Capacity WG - meeting #1 summary

Apologies, attached is a cleaner version.
Karen

From: Tountas, Karen (FNIH) [T]
Sent: Thursday, April 16, 2020 6:10 AM
To: Bascles, Lionel <(b) (6)> Cohen, Myron (b) (6) Corey, Larry
(b) (6) ; Desrosiers, Betsy <(b) (6)> >; Dickens, Jim (NIH/NCATS) [C]
(b) (6) >; Doroshow, James (NIH/NCI) [E] <(b) (6)> Goff, David (NIH/NHLBI) [E]

< (b) (6) King, James < (b) (6) Kurilla, Mike < (b) (6) Nayak, Seema (NIH/NIAID)
 [E] <seema.naya(b) (6).gov>; Parker, Ashley (NIH/OD) [E] (b) (6) >; Payton, Manzine
 (b) (6) >; Resnansky, Laura (b) (6) >; Srinivasan, Badhri
 (b) (6) ; Stein, Peter (FDA/CDER) (b) (6) >; Vincent, Mike
 (b) (6) >; Woodcock, Janet (FDA/CDER) (b) (6)
Cc: Colvis, Christine (NIH/NCATS) [E] (b) (6) ; Hughes, Eric (b) (6) >; Jansen,
 Kathrin (b) (6) >; Lowy, Douglas (NCI) < (b) (6) >, Read, Sarah (NIH/NIAID) [E]
 (b) (6) ; Young, John (b) (6) >; Criffield, Robin <robin (b) (6)
 Hamilton, Nancy (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6) ; Minnich, Beth
 (b) (6) Rebecca (NIH/NCATS) Katz [E] (b) (6) Thomas,
 Ashley (FDA/CDER) (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) >, Anderson, Margaret
 < (b) (6) Carluccio, Dana (b) (6) Cheryl (FNIH) Melencio [T]
 (b) (6) Gonzalez, Nina (b) (6) >; Heaton, Penny
 (b) (6) ; James, Stephanie < (b) (6) Li, Rose < (b) (6)
 Menetski, Joseph (FNIH) [T] < (b) (6) Santos, Michael (FNIH) < (b) (6) Tuveeson, Nancy
 (b) (6) ; Wholley, David (FNIH) [T] (b) (6) Wachtel, Jonathan

Subject: Clinical Trial Capacity WG - meeting #1 summary

Dear Clinical Trial Capacity Working Group colleagues,

Attached is a summary of meeting #1 of the Clinical Trial Capacity Working Group. It was a very good start to this effort; thank you to everyone for participating in this important initial discussion.

Looking forward to forming the subgroups and initiating detailed activities
 Karen

Karen H. Tountas, PhD
 Scientific Program Manager
 Foundation for the National Institutes of Health
 (b) (6) : [fnihi.org](mailto:(b) (6)@fnihi.org)
 11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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Sent: 2/17/2021 1:06:01 PM
Subject: FW: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021
Attachments: 02.17.21 ACTIV EC and Leadership Team Meeting 20210216_vF.pdf; 02.17.21 ACTIV EC and Leadership Team Meeting_APPENDIX 20210216 vF.pdf; 2021-01-14 ACTIV Leadership Team and Executive Committee Meeting_Summary vF.pdf

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, February 16, 2021 7:03 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael
<(b) (6)> Embry, Alan (NIH/NIAID) [E] <(b) (6)> Erbeling, Emily (NIH/NIAID) [E]
<(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>
Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary
(NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lepore, John <(b) (6)>
Marks, Peter (FDA/CBER) <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker,
David <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Messonnier, Nancy
(CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene
<(b) (6)> Pao, William <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Paul, Steve <(b) (6)> Perlmutter, Roger <(b) (6)>
Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni
<(b) (6)> Reed, John <(b) (6)> Reese, David <(b) (6)> Rouse, Doris
<(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky, Daniel <(b) (6)>
Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul <(b) (6)> Tabak, Lawrence (NIH/OD)
[E] <(b) (6)> Talley, Michael <(b) (6)> Tsai, John <(b) (6)>
Vessey, Rupert <(b) (6)> Virgin, Skip <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)>
Woodcock, Janet (FDA/OC) <(b) (6)> Young, John <(b) (6)> Colvis,
Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Eric
Hughes <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Young, John <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)>
Carluccio, Dana <(b) (6)> Castillejos, Carlos <(b) (6)> Culp, Michelle
(NIH/OD) [E] <(b) (6)> FNIH Central Account <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lumsden, Joanne (NIH/NCATS) [C]
<(b) (6)> Myles, Renate (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]
<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Margaret Anderson
<(b) (6)> Appell, Evan <(b) (6)> Chen, Helen <(b) (6)>
Connelly, Sarah <(b) (6)> Dally, Nicole <(b) (6)> Gonzalez, Nina
<(b) (6)> Hawk, Harrison <(b) (6)> Mendelson, Jesse <(b) (6)>
Menetski, Joseph (FNIH) [T] <(b) (6)> Nasr, Hana <(b) (6)> Santos, Michael (FNIH) [T]
<(b) (6)> Sorosa, Alex <(b) (6)> Stratton, Benjamin <(b) (6)> Tolman,
Brett <(b) (6)> Wachtel, Jonathan <(b) (6)> Wholley, David (FNIH) [T]
<(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E]
<(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)> Myles, Renate (NIH/OD) [E]

< (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6)

Subject: ACTIV Joint Executive Committee & Leadership Team Meeting: tomorrow, February 17, 2021

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, February 17, from 11:30 a.m. to 1:00 p.m. Eastern U.S. Time.** The minutes from the January 14 Executive Committee/Leadership Team call are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 11/6/2020 6:01:02 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
(b) (6) Lowy, Douglas (NIH/NCI) [E] | (b) (6) (b) (6)
Arvin, Ann | (b) (6) ; Beth Bell | (b) (6) | (b) (6)
(b) (6) Cavaleri Marco | (b) (6) (b) (6)
(b) (6) (b) (6) Greg Glenn | (b) (6) |;
(b) (6) Haynes, Barton | (b) (6) (b) (6) (b) (6)
Marks, Peter (FDA/CBER) | (b) (6) Mascola, John (NIH/VRC) [E] | (b) (6)
Messonnier, Nancy (CDC/DDID/NCIRD/OD) | (b) (6) Nelson Michael | (b) (6) il);
Offit, Paul | (b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA)
| (b) (6) |; (b) (6) (b) (6) Tal Zaks
| (b) (6)
CC: btolman | (b) (6) |; (b) (6) Hopps, Markay | (b) (6)
Kozlowski, Mary (NIH/NCI) [C] | (b) (6) |; Johnson, Maureen (NIH/NCI) [E]
| (b) (6) (b) (6) Jeneffer Haynes | (b) (6) |.
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
| (b) (6) (b) (6) Isabel Ramsey | (b) (6) Parker,
Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Marston, Henry
(NIH/NIAID) [E] | (b) (6) Erbelding, Emily (NIH/NIAID) [E] | (b) (6) Deffenbach,
Carl (NIH/NIAID) [E] | (b) (6) Qashu, Felicia (NIH/OD) [E] | (b) (6) Culp, Michelle
(NIH/OD) [E] | (b) (6) Gadbois, Ellen (NIH/OD) [E] | (b) (6) Wholley, David (FNIH) [T]
| (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Menetski, Joseph (FNIH) [T]
| (b) (6) Adam, Stacey (FNIH) [T] | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6)
James, Stephanie (FNIH) [T] | (b) (6) Colvis, Christine (NIH/NCATS) [E] | (b) (6)
Desrosiers, Betsy | (b) (6) Eric Hughes | (b) (6) Kurilla, Michael
(NIH/NCATS) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Paul Gillard
| (b) (6) |; François P Roman | (b) (6) Hamilton, Holli (OS/ASPR/BARDA)
| (b) (6) Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)
| (b) (6) Kathleen Neuzil | (b) (6) Martin, Stacey
(CDC/DDID/NCEZID/DVBD) | (b) (6) McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD) | (b) (6)
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) | (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD)
(b) (6) Lindsey, Nicole (CDC/DDID/NCEZID/DVBD) (b) (6) Thornburg, Natalie
(CDC/DDID/NCIRD/DVD) | (b) (6) 'Wachtel, Jonathan' | (b) (6) |, Stratton, Benjamin
| (b) (6) Margaret Anderson | (b) (6) (b) (6)
(b) (6) Bethany Stokes | (b) (6) Kathleen Callahan
| (b) (6) Molloy, Delia (DPH) | (b) (6) Wood, Gretchen (NIH/OD) [E]
| (b) (6) Filip Dubovsky | (b) (6) Michael Watson (x)
| (b) (6) Antonio Lanzavecchia | (b) (6) Arvin, Ann
| (b) (6) Harris, Rebecca /SG | (b) (6) |; Vivek Shinde | (b) (6) |;
Cohen, Myron | (b) (6) Criffield, Robin R. | (b) (6) Marovich, Mary
(NIH/NIAID) [E] | (b) (6) Young, John | (b) (6) Gonzalez, Nina
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
Jacqueline Miller | (b) (6)

Subject: ACTIV Vaccines Working Group meeting
Location: <https://fnih.zoom.us/j/> (b) (6)
Start: 11/11/2020 6:00:00 PM
End: 11/11/2020 7:00:00 PM
Show Time As: Busy

Required Attendees:	(b) (6)	Lowy, Douglas (NIH/NCI) [E];	(b) (6)	Arvin, Ann; Beth Bell
	(b) (6)	(b) (6)	Cavaleri Marco;	(b) (6)
	(b) (6)	(b) (6)	Greg Glenn;	(b) (6) Haynes,
	Barton, (b) (6)	(b) (6)	Marks, Peter (FDA/CBER);	Mascola, John (NIH/VRC) [E],
	Messonnier, Nancy (CDC/DDID/NCIRD/OD);	Nelson Michael; Offit, Paul;	(b) (6)	Seals, Jonathan
	(OS/ASPR/BARDA);	(b) (6)	(b) (6)	Tal Zaks
Optional Attendees:	Tolman, Brett;	(b) (6)	Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C];	Johnson, Maureen
	(NIH/NCI) [E];	(b) (6)	Jeneffer Haynes;	(b) (6)
	(b) (6)	Austin, Sarah (NIH/NIAID) [E];	(b) (6)	Isabel Ramsey; Parker,
	Ashley (NIH/OD) [E];	Marston, Hilary (NIH/NIAID) [E];	Erbelding, Emily (NIH/NIAID) [E];	Dieffenbach, Carl (NIH/NIAID)
	[E]; Qashu, Felicia (NIH/OD) [E];	Culp, Michelle (NIH/OD) [E];	Gadbois, E len (NIH/OD) [E];	Wholley, David (FNIH) [T];
	Melencio, Cheryl (FNIH) [T];	Menetski, Joseph (FNIH) [T];	Adam, Stacey (FNIH) [T];	Tountas, Karen (FNIH) [T];
	James, Stephanie (FNIH) [T];	Colvis, Christine (NIH/NCATS) [E];	Desrosiers, Betsy; Hughes, Eric;	Kurilla, Michael (NIH/NCATS)
	[E]; Read, Sarah (NIH/NIAID) [E];	Young, John; Paul Gillard;	François P Roman; Hamilton, Holli (OS/ASPR/BARDA);	
	Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA);	Kath een Neuzil; Martin, Stacey	(CDC/DDID/NCEZID/DVBD);	McNamara, Lucy Alexandra (CDC/DDID/NCIRD/DBD);
	Schrag, Stephanie	(CDC/DDID/NCIRD/DBD);	Verani, Jennifer R. (CDC/DDID/NCIRD/DBD);	Lindsey, Nicole (CDC/DDID/NCEZID/DVBD);
	Thornburg, Natalie (CDC/DDID/NCIRD/DVD);	Gonzalez, Nina; Wachtel, Jonathan;	Stratton, Benjamin; Anderson,	Margaret;
	(b) (6)	(b) (6)	Bethany Stokes; Kathleen Callahan;	
	Moiloy, Delia (DPH);	Wood, Gretchen (NIH/OD) [E];	Filip Dubovsky; Michael Watson (x);	Jacqueline Miller; Antonio
	Lanzavetchia; Ann Arvin; Harris, Rebecca /SG;	Vivek Shinde; Cohen, Myron; Criffeld, Robin R.;	Marovich, Mary	(NIH/NIAID) [E]

Michael Santos is inviting you to a scheduled Zoom meeting.

Topic: ACTIV Vaccines Working Group meeting

Time: Nov 11, 2020 01:00 PM Eastern Time (US and Canada)

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US (Tacoma)
US (Houston)
US (San Jose)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom.u> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/16/2020 10:24:23 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan (b) (6)]; Collins, Sylva (FDA/CDER) [Sylva.Col (b) (6) Judy Currier (b) (6) De Claro, R. Angelo (FDA/CDER) [(b) (6) Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M. (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Amanda Peppercorn | (b) (6)]; Price, Dionne (FDA/CDER) | (b) (6) Rubin, Daniel B. (FDA/CDER) | (b) (6) Shen, Yuan Li (FDA/CDER) | (b) (6) Farley, John (FDA/CDER) (b) (6)]; Goff, David (NIH/NHLBI) [E] | (b) (6) Vincent, Michael | (b) (6)
CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6) Wachtel, Jonathan (b) (6) Elizabeth Kim | (b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account | (b) (6) Lucas Smalldon | (b) (6) Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] | (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Wung, Peter /US | (b) (6)

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #4

Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_21Apr2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting Agenda_04212020.pdf; D. Goff network capacity template_04202020.xlsx; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 3 Key Takeaways_04202020.pdf

Location: <https://fnih.zoom>. (b) (6)

Start: 4/21/2020 5:00:00 PM

End: 4/21/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael

Optional Attendees: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Wung, Peter /US

Dear ACTIV TX-Clinical Master Protocol SG,

Please find attached the materials for today's call. Apologies for the slight delay in sending.

1. Agenda
2. Slides for Discussion – Updated Timelines for feedback and then questions to consider for the two master protocols to start deciding design.
3. Clinical Trial Network Survey – the CTC WG would like any feedback we might have about other needed information.
4. High level update from yesterday

We look forward to speaking with you today.

Thanks,
Stacey

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Sent: 6/13/2020 5:15:39 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: Time sensitive: Making your ACTIV Participation Public
Attachments: Leadership National Institutes of Health (NIH) pdf; 1-Draft NIH ACTIV Webpage Content 5.14.2020 w changes updated editsLBAP.docx

Hi Renate,

Sparing FC's inbox and others.

With many thanks to Lauren for helping us with this. Please see edits attached and below – the alphabetizing of the names can be ignored as this is updated in the revised version you've provided.

A few minor edits:

- Co-chairs of the working groups should be identified
- Consistency with MD or M.D.
- Minor change to John Mellors

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 15, 2020 9:21 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)> ; Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Allen-Gifford, Patricia (NIH/OD) [E] <(b) (6)> ; Wooldridge, Shannon (NIH/OD) [E] <(b) (6)> ; Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Ashley:

Attached is the full list of members currently listed on the website in staging. I received the list from FNIH communications. Please let me know of any changes.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 15, 2020 9:11 AM
To: Myles, Renate (NIH/OD) [E] <(b) (6)> ; Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Allen-Gifford, Patricia (NIH/OD) [E] <(b) (6)> ; Wooldridge, Shannon (NIH/OD) [E] <(b) (6)> ; Pollock, Rachel (NIH/OD) [E] <(b) (6)>
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Hi Renate,

I've added the emails below but we have a major version control issues. I've been working with Cheryl to receive updates and did not have Sylvia Collins, Beth Bell and Jonathan Seals and apparently they are listed on a separate list the FNIH communications team is tracking.

We can send follow up emails to everyone except for those three – they will need to be contacted.

Moving forward, it may be best for you to receive updates from the communications team – FNIH is managing multiple spreadsheets one for the emails Cheryl is managing to schedule meetings and a separate list for the communications office.

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

(b) (6)

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

(b) (6)

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

(b) (6)

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

(b) (6)

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

(b) (6)

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

(b) (6)

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

(b) (6)

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

(b) (6)

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

(b) (6)

Frank Stegmeier, Ph.D.

Chief Scientific Officer

KSQ Therapeutics

(b) (6)

Sylva Collins, Ph.D.

Director, Office of Biostatistics

U.S. Food and Drug Administration

(b) (6)

Judith Currier, M.D.

Professor of Medicine

University of California Los Angeles

Division of Infectious Diseases

Chair, AIDS Clinical Trial Group (ACTG)

(b) (6)

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

(b) (6)

Elliot Levy, M.D.

Senior Vice President, Global Development

Amgen

(b) (6)

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations

Sanofi

(b) (6)

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs

Eli Lilly and Company

(b) (6)

Peter Stein, M.D.

Director of Office of New Drugs

Center for Drug Evaluation and Research

U.S. Food and Drug Administration

(b) (6)

Beth Bell, M.D., MPH

Clinical Professor, Global Health

University of Washington

(b) (6)

Emilio Emini, Ph.D.

Director, TB & HIV Program

Bill & Melinda Gates Foundation

(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

(b) (6)

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

(b) (6)

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

(b) (6)

From: Myles, Renate (NIH/OD) [E] (b) (6)

Sent: Friday, May 15, 2020 7:53 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Allen-Gifford, Patrice (NIH/OD) [E] (b) (6) Parker, Ashley (NIH/OD) [E]

(b) (6) Wooldridge, Shannon (NIH/OD) [E] (b) (6) Pollock, Rachel (NIH/OD)

[E] < (b) (6)

Subject: FW: Time sensitive: Making your ACTIV Participation Public

Hi Francis:

Below is the list of 23 vpeople who have not yet responded to your email. I cross referenced these names with the email list that Ashley sent and pulled addresses from that list. I didn't find emails for a number of these people, but I know there was a second round that went out using emails I don't have. Hoping Ashley can provide the missing emails.

(b) (6)

Ralph Baric, Ph.D.

William R. Kenan, Jr., Distinguished Professor, Department of Epidemiology
Professor, Department of Microbiology and Immunology
University of North Carolina, Gillings School of Global Public Health

Damon Deming, Ph.D.

Virologist, Division of Antiviral Products, Office of New Drugs
U.S. Food and Drug Administration

Greg Gatto, Ph.D.

Drug Development Regulatory Project Leader
RTI International

Jay Grobler, Ph.D.

Director, Infectious Disease Biology
Merck & Co., Inc.

Cat Lutz, Ph.D.

Senior Director, Mouse Repository & In Vivo Pharmacology, Rare and Orphan Disease Center
The Jackson Laboratory

David Payne, Ph.D.

Vice President & Head, Medicine Opportunities Research Unit
GlaxoSmithKline

Louise Pitt, Ph.D.

Director, Center for Aerobiological Sciences
United States Army Medical Research Institute of Infectious Diseases

Srinivas Rao, DVM, Ph.D.

Global Head, Translational In Vivo Models Global Research Platform
Sanofi

Jay Rappaport, Ph.D.

Professor of Microbiology and Immunology
Director and Chief Academic Officer
Tulane University National Primate Research Center

Frank Stegmeier, Ph.D.

Chief Scientific Officer
KSQ Therapeutics

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

Judith Currier, M.D.

Professor of Medicine
University of California Los Angeles
Division of Infectious Diseases
Chair, AIDS Clinical Trial Group (ACTG)

(b) (6)

John Farley, M.D., M.P.H.

Director, Office of Infectious Diseases
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Elliot Levy, M.D.

Senior Vice President, Global Development
Amgen

(b) (6)

Lionel Bascles, Ph.D.

Senior Vice President, Global Head of Clinical Sciences & Operations
Sanofi

(b) (6)

Carlos Garner, Ph.D.

Vice President, Global Regulatory Affairs
Eli Lilly and Company

(b) (6)

Peter Stein, M.D.

Director of Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

(b) (6)

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

Emilio Emini, Ph.D.

Director, TB & H.V Program
Bill & Melinda Gates Foundation

(b) (6)

Kathrin Jansen, Ph.D.

Senior Vice President and Head of Vaccine Research and Development
Pfizer

(b) (6)

Antonio Lanzavecchia, M.D.

Senior Vice President and Senior Research Fellow
Vir Biotechnology, Inc.
Director, Institute for Research in Biomedicine, Bellinzona, Switzerland

(b) (6)

Nancy Messonnier, M.D.

Director, Center for the National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

(b) (6)

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

From: Collins, Francis (NIH/OD) [E] < (b) (6) >

Sent: Thursday, May 14, 2020 11:00 AM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Myles, Renate (NIH/OD) [E] -

Meltzer, Abbey (FNIH) [T] <

(b) (6) >

>; Wholley, David

(FNIH) [T] < (b) (6)

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot, Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael, Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn, Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6)
Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;
(b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Menetski, Joseph (FNIH) [T]; Dana Carluccio; Rose Li Centra; Account; Lucas Sma; Idon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, H lary (NIH/N AID) [E]; Chen, Helen; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kndzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Dally, Nicolle

Stacey Adam is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting
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Meeting ID: (b) (6)
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US (San Jose)
US (Tacoma)
US (Houston)
US (San Jose)

Meeting ID: (b) (6)
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Find your local number: <https://fnih.zoom.us> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/19/2020 10:12:59 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdener, Keith | (b) (6) Hughes, Eric | (b) (6) Judy Currier
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6)
CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: Time Sensitive Request for Response from ACTIV Therapeutics-Clinical Working Group

Dear ACTIV Working Group Members,

To follow up on the request to publicly list your name associated with this ACTIV working group, we wanted to provide a bit more context.

As you may have heard on Friday, Dr. Francis Collins hosted a national news telebriefing with more than a dozen journalists from a variety of publications. Overall, the feedback was positive and some of the resulting articles can be found attached. Several reporters have subsequently asked for a list of those participating in ACTIV. We will not make this information public without the prior approval of the participants and their organizations. Therefore, we are checking with you as to whether you are willing to make your name, title, and company/institution available for this purpose. Should you prefer to withhold your name in this context, we will of course honor your wishes.

Again, please send your approval to Abbey Meltzer, FNIH's VP of Communications, at (b) (6) or reach out with any questions.

Best,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]

Sent: Sunday, April 19, 2020 4:40 PM

Subject: Time Sensitive Request for Response from ACTIV Therapeutics-Clinical Working Group

Importance: High

Dear ACTIV Therapeutics-Clinical Working Group Members,

I hope this message finds you well. I am writing to seek your approval to publicly list your name in association with this ACTIV working group. A reporter has reached out to the FNIH asking for the names of the working group members, and we would like to point them to a listing of these names on the FNIH website, once you have provided clearance for this.

The FNIH's Vice President of Communications and Events, Abbey Meltzer, will be tracking these approvals, so please send your approval to her at (b) (6) If you have any questions, please do not hesitate to reach out to Abbey.

Best,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: (b) (6) Mobile: (b) (6)

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/15/2020 6:08:29 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups
Attachments: Master list for ACTIV 041520.xlsx

Francis -- the following emails were missing from the list that went out, please see 8 emails listed below

Cheryl -- attached is a revised master list (114 contacts) with names and emails which includes everyone.

Disbrow, Gary (OS/ASPR/BARDA) < (b) (6)
Kim, Elizabeth < (b) (6)
Marston, Hilary (NIH/NIAID) [E] (b) (6)
Paul, Steve < (b) (6)
Payne, David < (b) (6) ;
Plump, Andy (b) (6) >;
Santos, Nanry (b) (6) ;
Shen, Yuan Li (FDA/CDER) (b) (6)

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] < (b) (6)
Sent: Wednesday, April 15, 2020 11:39 AM
To: Melencio, Cheryl (FNIH) [T] < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)
Subject: RE: List -- just copy and paste in bcc. lists of April 3 plus working groups

I already sent the other list, given the time sensitivity. What has been added here that wasn't in the other one?

From: Melencio, Cheryl (FNIH) [T] (b) (6)
Sent: Wednesday, April 15, 2020 11:19 AM
To: Parker, Ashley (NIH/OD) [E] <ashl (b) (6) Collins, Francis (NIH/OD) [E] <col (b) (6)
Subject: List -- just copy and paste in bcc. lists of April 3 plus working groups

Austin, Christopher (NIH/NCATS) [E] < (b) (6) Bright, Rick < (b) (6) Collins, Francis (NIH/OD) [E] (b) (6) >; Corey, Larry (b) (6) ; Disbrow, Gary (OS/ASPR/BARDA) < (b) (6) ; Dolsten, Mikael (b) (6) ; Erbeling, Emily (NIH/NIAID) [E] < (b) (6) ; Fauci, Anthony (NIH/NIAID) [E] <afauc (b) (6) >; Frankowski, David < (b) (6) Hudson, Thomas < (b) (6) James, Stephanie (FNIH) [T] (b) (6) Klock, Kevin (FNIH) [T] (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Marks, Peter (FDA/CBER) (b) (6) >; Marston, Hilary (NIH/NIAID) [E] (b) (6) >; Mascola, John (b) (6) Meeker, David (b) (6) ; Menetski, Joseph (FNIH) [T] (b) (6) Pangalos, Mene <m (b) (6) ; Pao, William (b) (6) ; Paul, Steve (b) (6) >; Perlmutter, Roger < (b) (6) ; Plump, Andy (b) (6) ; Rasi, Guido < (b) (6) Reed, John (b) (6) ; Rouse,

Doris < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) : Skovronsky, Daniel
 (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) : Stoffels, Paul
 < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) Tsai, John
 (b) (6) >; Vessey, Rupert (b) (6) : Virgin, Skip < (b) (6) >; Wholley, David
 (FNIH) [T] < (b) (6) >; Woodcock, Janet (FDA/CDER) (b) (6) Young, John
 (b) (6) ; Adam, Stacey (FNIH) [T] < (b) (6) : Bascles, Lionel
 (b) (6) >; Cohen, Myron (b) (6) ; Corey, Larry (b) (6) ;
 Desrosiers, Betsy (b) (6) : Dickens, Jim (NIH/NCATS) [C] < (b) (6)
 Doroshov, James (NIH/NCI) [E] (b) (6) : Goff, David (NIH/NHLBI) [E] (b) (6) ; Heaton,
 Penny (b) (6) ; King, James (b) (6) ; Kurilla, Mike (b) (6) >; Nayak,
 Seema (NIH/NIAD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] < (b) (6) ; Payton, Manzine
 (b) (6) >; Resnansky, Laura < (b) (6) >; Srinivasan, Badhri
 (b) (6) ; Stein, Peter (FDA/CDER) (b) (6) ; Tountas, Karen (FNIH) [T]
 (b) (6) >; Vincent, Mike (b) (6) : Wachtel, Jonathan (b) (6) >;
 Woodcock, Janet (FDA/CDER) < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) Bozzette,
 Sam (NIH/NCATS) [E] (b) (6) ; Buchman, Tim (OS/ASPR/BARDA) (CTR) (b) (6) >;
 Butters, Joan (b) (6) : De Claro, R. Angelo (FDA/CDER) < (b) (6) >;
 Draghia-Akli, Ruxandra < (b) (6) : Eisner, Mark < (b) (6) Gottesdiener, Keith
 < (b) (6) >; Hughes, Eric (b) (6) >; Judy Currier
 < (b) (6) Kim, Elizabeth (b) (6) ; LaVange, Lisa < (b) (6) Levy, Elliot
 < (b) (6) Mellors, John < (b) (6) Menon, Sandeep < (b) (6) : Parker,
 Ashley (NIH/OD) [E] (Patel, Naimish (b) (6) >; Peppercorn, Amanda
 < (b) (6) Poole, Mike < (b) (6) Proschan, Michael
 < (b) (6) Read, Sarah < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) Shen,
 Yuan Li (FDA/CDER) (Stein, Peter (FDA/CDER) < (b) (6) Adams, Peter
 (OS/ASPR/BARDA) (b) (6) Alvarez, Rosa < (b) (6) Anderson, Annaliesia
 (Baric, Ralph (b) (6) ; Carter, Kara < (b) (6)
 Colvis, Christine (b) (6) >; Deming, Damon (FDA/CDER) (b) (6) Diamond,
 Michael (b) (6) >; Duncan, Ken (b) (6) ; Fernandes, Prabhavathi
 (b) (6) >; Gatto, Greg (b) (6) Grobler, Jay < (b) (6) Hewitt, Judith
 (b) (6) ; Jonson, Samantha (NIH/NCATS) [E] (b) (6) ; Lutz, Cat (b) (6) >;
 Menetski, Joseph (FNIH) [T] (b) (6) >; Nestle, Frank (b) (6) >; Ottinger, Liz
 <ottingerea@mail.nih.gov>; Parker, Ashley (NIH/OD) [E] < (b) (6) : Payne, David
 < (b) (6) Rappaport, Jay (b) (6) >; Stegmeier, Frank (b) (6) >;
 Young, John < (b) (6) Annunziato, Paula < (b) (6) Arvin, Ann
 < (b) (6) >; Buchbinder, Susan (b) (6) ; Corey, Larry (b) (6) >;
 Davis, Mark < (b) (6) Ermini, Emilio (b) (6) ; Hanon, Emmanuel
 < (b) (6) ; Haynes, Barton < (b) (6) Hotez, Peter < (b) (6) Jansen,
 Kathrin < (b) (6) ; Lanzavecchia, Antonio (b) (6) >; Lowy, Douglas (NIH/NCI) [E]
 < (b) (6) Marks, Peter (FDA/CDER) < (b) (6) Mascola, John (NIH/VRC) [E]
 (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) < (b) (6) : Offit, Paul
 (b) (6) ; Parker, Ashley (NIH/OD) [E] (b) (6) ; Santos, Nancy (b) (6) ;
 Schuitemaker, Hanneke (b) (6) Tartaglia, Jim < (b) (6) ; Tolman, Brett
 (b) (6) (b) (6) (b) (6)

Cheryl Melencio

Administrative Manager, Research Partnerships
 Foundation for the National Institutes of Health
 (b) (6)

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Sent: 12/16/2020 2:40:18 PM
Subject: FW: ACTIV Leadersh p Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION
Attachments: 12.16 ACTIV EC and Leadersh p Team Meeting 20201215_vF (003).pdf; 12.16 ACTIV EC and Leadership Team Meeting_APPENDIX 20201215 vF.pdf; 2020-11-19 ACTIV Leadership Team Meeting_Summary v3.pdf

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 6:29 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
Bancel, Stephane <(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Victoria Davey <(b) (6)> Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael
<(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan
<(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Freire, Maria (FNIH) [T]
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E]
<(b) (6)> Hudson, Thomas <(b) (6)> James, Stephanie (FNIH) [T]
<(b) (6)> Johnson, Robert (OS/ASPR/BARDA) <(b) (6)> Kramer, Lynn
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Lepore, John <(b) (6)>
Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary (NIH/NIAID) [E] <(b) (6)>
Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David <(b) (6)> Menetski, Joseph
(FNIH) [T] <(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh
<(b) (6)> Pangalos, Mene <(b) (6)> Pao, William
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Paul, Steve <(b) (6)>
Perlmutter, Roger <(b) (6)> Plenge, Robert <(b) (6)> Plump, Andy
<(b) (6)> Rachel Ramoni <(b) (6)> Reed, John <(b) (6)> Reese,
David <(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)>
Skovronsky, Daniel <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Stoffels, Paul
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Talley, Michael
<(b) (6)> Tsai, John <(b) (6)> Vessey, Rupert <(b) (6)> Virgin, Skip
<(b) (6)> Woodcock, Janet (FDA/CDER) <(b) (6)> Young, John
<(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy
<(b) (6)> Eric Hughes <(b) (6)> Jansen, Kathrin
<(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI)
<(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)>
Adam, Stacey (FNIH) [T] <(b) (6)> Margaret Anderson <(b) (6)> Appell, Evan
<(b) (6)> Chen, Helen Q. <(b) (6)> Connelly, Sarah <(b) (6)>
Gonzalez, Nina <(b) (6)> Hawk, Harrison <(b) (6)> Mendelson, Jesse
<(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Nasr, Hana <(b) (6)>
Santos, Michael (FNIH) [T] <(b) (6)> Sorosa, Alex David <(b) (6)> Stratton, Benjamin
<(b) (6)> btolman <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)>
Wachtel, Jonathan <(b) (6)>
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E]
<(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Carluccio, Dana
<(b) (6)> Castillejos, Carlos <(b) (6)> FNIH Central Account
<(b) (6)> Hallett, Adrienne (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E]
<(b) (6)> Myies, Renate (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Wolinetz, Carrie (NIH/OD) [E]
<(b) (6)> Meltzer, Abbey (FNIH) [T] <(b) (6)>
Subject: RE: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020 -- CORRECTION

Dear ACTIV Leadership Team and meeting attendees:

Please see corrected version of materials. Sorry for the confusion.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, December 15, 2020 5:08 PM
To: Austin, Christopher (NIH/NCATS) | (b) (6) >; Bancel, Stephane
(b) (6) Carter, Kara (b) (6) Cavaleri, Marco
(b) (6) ; Cihlar, Tomas (b) (6) Collins, Francis (NIH/OD) [E]
< (b) (6) Corey, Larry < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6)
Victoria Davey (b) (6) >; Disbrow, Gary (OS/ASPR/BARDA) (b) (6) >, Dolsten, Mikael
(b) (6) ; Erbelding, Emily (NIH/NIAID) [E] < (b) (6) Erck, Stan
< (b) (6) Fauci, Anthony (NIH/NIAID) [E] < (b) (6) >; Freire, Maria (FNIH) [T]
< (b) (6) Gadbois, Ellen (NIH/OD) [E] (b) (6) Gibbons, Gary (NIH/NHLBI) [E]
< (b) (6) ; Hudson, Thomas < (b) (6) James, Stephanie (FNIH) [T]
< (b) (6) Johnson, Robert (OS/ASPR/BARDA) < (b) (6) Kramer, Lynn
(b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Lepore, John (b) (6) >;
Marks, Peter (FDA/CBER) (b) (6) ; Marston, Hilary (NIH/NIAID) [E] < (b) (6) ;
Mascola, John (NIH/VRC) [E] (b) (6) Meeker, David < (b) (6) Menetski, Joseph
(FNIH) [T] < (b) (6) >; Messonnier, Nancy (CDC/DDID/NCIRD/OD) (b) (6) Pandya, Hitesh
< (b) (6) Pangalos, Mene (b) (6) >; Pao, William
(b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) ; Paul, Steve < (b) (6)
Perlmutter, Roger < (b) (6) Plenge, Robert < (b) (6) Plump, Andy
< (b) (6) Rachel Ramoni < (b) (6) Reed, John (b) (6) >; Reese,
David (b) (6) ; Rouse, Doris < (b) (6) ; Santos, Michael (FNIH) [T] (b) (6)
Skovronsky, Daniel < (b) (6) Stein, Peter (FDA/CDER) < (b) (6) ; Stoffels, Paul
(b) (6) ; Tabak, Lawrence (NIH/OD) [E] < (b) (6) >; Talley, Michael
(b) (6) ; Tsai, John (b) (6) >; Vessey, Rupert (b) (6) ; Virgin, Skip
< (b) (6) Wholley, David (FNIH) [T] < (b) (6) Woodcock, Janet (FDA/CDER)
< (b) (6) Young, John < (b) (6) Colvis, Christine (NIH/NCATS) [E]
< (b) (6) >; Desrosiers, Betsy (b) (6) Eric Hughes
< (b) (6) ; Jansen, Kathrin < (b) (6) Kurilla, Michael (NIH/NCATS) [E]
< (b) (6) Lowy, Douglas (NCI) < (b) (6) >; Read, Sarah (NIH/NIAID) [E] < (b) (6)
Young, John (b) (6) ; Adam, Stacey (FNIH) [T] (b) (6) Margaret Anderson

< (b) (6) Appell, Evan < (b) (6) Chen, Helen Q. < (b) (6)
 Connelly, Sarah (b) (6) ; Gonzalez, Nina (b) (6) ; Hawk, Harrison
 < (b) (6) Mendelson, Jesse (b) (6) Menetski, Joseph (FNIH) [T]
 (b) (6) Nasr, Hana < (b) (6) ; Santos, Michael (FNIH) [T] < (b) (6) >; Sorosa,
 Alex David < (b) (6) Stratton, Benjamin < (b) (6) btolman < (b) (6)
 Tountas, Karen (FNIH) [T] (b) (6) Wachtel, Jonathan (b) (6) ; Wholley, David (FNIH) [T]
 < (b) (6)
Cc: Anderson, James (NIH/OD) [E] (b) (6) ; Austin, Christopher (NIH/NCATS) [E]
 (b) (6) >; Burklow, John (NIH/OD) [E] (b) (6) ; Carluccio, Dana
 < (b) (6) Castillejos, Carlos < (b) (6) >; FNIH Central Account
 (b) (6) ; Hallett, Adrienne (NIH/OD) [E] (b) (6) Lane, Cliff (NIH/NIAID) [E]
 (b) (6) >; My.es, Renate (NIH/OD) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E]
 (b) (6) ; Tabak, Lawrence (NIH/OD) [E] < (b) (6) ; Wolinetz, Carrie (NIH/OD) [E]
 (b) (6) Meltzer, Abbey (FNIH) [T] (b) (6)
Subject: ACTIV Leadership Team Meeting, Tomorrow, December 16, 2020

Dear ACTIV Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow, Wednesday, December 16, 10:00 – 11:30 a.m. Eastern U.S. Time**. The minutes from the November 19 Leadership Team call are attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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· US (Chicago)

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US (New York)

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US (San Jose)

US (Tacoma)

US (Houston)

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Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom>. (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/7/2020 8:56:23 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes
[(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Ruxandra Draghia-Akli
(b) (6) Mellors, John W (b) (6) Naimish Patel [(b) (6) Colvis,
Christine (NIH/NCATS) [E] [(b) (6) Young, John (b) (6)]; Stein, Peter
(FDA/CDER) [(b) (6) Poole, Mike [(b) (6) Buchman, Tim
(OS/ASPR/BARDA) (CTR) [(b) (6) Vincent, Michael [(b) (6) Keith
Gottesdiener [(b) (6) Elliott Levy [(b) (6) Wung, Peter /US
[(b) (6) Koroshetz, Walter (NIH/NINDS) [E] [(b) (6) Higgs, Elizabeth
(NIH/NIAID) [E] [(b) (6) Carlos O Garner [garner (b) (6) Goff, David (NIH/NHLBI) [E]
[(b) (6)
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] (b) (6) Alvarez, Rosa Maria
[(b) (6)]; Salathin, Carla [(b) (6) (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T]
[(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Lucas Smalidon
[(b) (6) Walker, Paula (NIH/NINDS) [E] [(b) (6)]; Ward, Jackie
(NIH/NINDS) [E] (b) (6)
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup #9
Location: <https://fnih.zoom.us/> (b) (6)
Start: 5/12/2020 5:00:00 PM
End: 5/12/2020 6:00:00 PM
Show Time As: Busy

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner; Goff, David (NIH/NHLBI) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalidon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

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US (Germantown)
US (Chicago)
US (San Jose)

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US (Houston)

US (San Jose)

Meeting ID: (b) (6)

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/30/2020 7:18:06 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
(b) (6) Lowy, Douglas (NIH/NCI) [E] | (b) (6) (b) (6)
Arvin, Ann | (b) (6) Beth Bell | (b) (6) | (b) (6)
(b) (6) Cavaleri Marco | (b) (6) (b) (6)
(b) (6) (b) (6) Greg Glenn | (b) (6)
(b) (6) Haynes, Barton | (b) (6) (b) (6) (b) (6)
Marks, Peter (FDA/CBER) | (b) (6) Mascola, John (NIH/VRC) [E] | (b) (6)
Messonnier, Nancy (CDC/DDID/NCIRD/OD) | (b) (6) Nelson Michael | (b) (6) ii);
Offit, Paul | (b) (6) (b) (6) Seals, Jonathan (OS/ASPR/BARDA)
| (b) (6) |; (b) (6) (b) (6) Tal Zaks
| (b) (6)
CC: Tolman, Brett | (b) (6) |; (b) (6) Hopps, Markay | (b) (6)
Kozlowski, Mary (NIH/NCI) [C] | (b) (6) |; Johnson, Maureen (NIH/NCI) [E]
| (b) (6) (b) (6) Jeneffer Haynes | (b) (6) |.
(b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
| (b) (6) (b) (6) Isabel Ramsey | (b) (6) Parker,
Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Henry
(NIH/NIAID) [E] | (b) (6) Qashu, Felicia (NIH/OD) [E] | (b) (6) Culp, Michel e
(NIH/OD) [E] | (b) (6) Gadbois, Ellen (NIH/OD) [E] | (b) (6) Wholley, David (FNIH) [T]
| (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Menetski, Joseph (FNIH) [T]
| (b) (6) Adam, Stacey (FNIH) [T] | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6)
James, Stephanie (FNIH) [T] | (b) (6) Colvis, Christine (NIH/NCATS) [E] | (b) (6)
Desrosiers, Betsy | (b) (6) Hughes, Eric | (b) (6) Kurilla, Michael
(NIH/NCATS) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Paul Gillard
| (b) (6) Hamilton, Holli (OS/ASPR/BARDA) | (b) (6) Modjarrad, Kayvon CIV
USARMY MEDCOM WRAIR (USA) | (b) (6) Kathleen Neuzil | (b) (6)
Schrage, Stephanie (CDC/DDID/NCIRD/DBD) | (b) (6) Veran, Jennifer R. (CDC/DDID/NCIRD/DBD)
(b) (6) Thornburg, Natalie (CDC/DDID/NCIRD/DVD) | (b) (6) Gonzalez, Nina
| (b) (6) 'Wachtel, Jonathan' | (b) (6) Stratton, Benjamin
| (b) (6) Anderson, Margaret | (b) (6) (b) (6)
(b) (6) Bethany Stokes | (b) (6) |; Kathleen Callahan
| (b) (6) Molloy, Delia (DPH) | (b) (6) Arvin, Ann | (b) (6)
Vivek Shinde | (b) (6) |; Young, John | (b) (6)

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex>. (b) (6)

Start: 7/22/2020 5:30:00 PM

End: 7/22/2020 6:30:00 PM

Show Time As: Busy

Required Attendees: Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6)
Arvin, Ann; Beth Bell | (b) (6) (b) (6) |; Cavaleri Marco; (b) (6)
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael, Offit, Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,

Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, M chelle (NIH/OD) [E]; Gadbois, El en (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melendo, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric, Kunlla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John, Paul Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil; Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret; (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Molloy, Delia (DPH); Ann Arvin; Vivek Shinde

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From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 11/13/2020 2:10:45 PM
To: Jessica (NIH/OD) Tucker [E] (b) (6) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2baf4ae78d90412dbef0fb5e52c31a4-tuckerjm]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: Post-Acute Sequelae of COVID19 Workshop Dec 3-4
Attachments: Post-AcuteCOVIDWorkshopAgenda.pdf

FYI. Maybe of broader OSP interest?

From: Adam, Stacey (FNIH) [T] < (b) (6) >
Sent: Friday, November 13, 2020 8:32 AM
To: Bozzette, Sam (NIH/NCATS) [E] < (b) (6) > Butterson, Joan < (b) (6) > De Claro, R. Angelo (FDA/CDER) < (b) (6) > Draghia-Akli, Ruxandra < (b) (6) > Eisner, Mark < (b) (6) > Gottesdiener, Keith < (b) (6) > Eric Hughes < (b) (6) > Judy Currier < (b) (6) > Kim, Elizabeth < (b) (6) > LaVange, Lisa < (b) (6) > Levy, Elliot < (b) (6) > Mellors, John W < (b) (6) > Menon, Sandeep < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) > Patel, Naimish < (b) (6) > Peppercorn, Amanda < (b) (6) > Poole, Mike < (b) (6) > Proschan, Michael (NIH/NIAID) [E] < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Santos, Michael (FNIH) [T] < (b) (6) > Shen, Yuan Li (FDA/CDER) < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Wholley, David (FNIH) [T] < (b) (6) > Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) > Collins, Sylvia (FDA/CDER) < (b) (6) > Amanda Peppercorn < (b) (6) > Garner, Carl < (b) (6) > Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) > Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) > Timothy Burgess < (b) (6) > Reineck, Lora (NIH/NHLBI) [E] < (b) (6) > Aggarwal, Neil (NIH/NHLBI) [E] < (b) (6) > Rosenberg, Yves (NIH/NHLBI) [E] < (b) (6) > Goff, David (NIH/NHLBI) [E] < (b) (6) > Brown, Jeremy (NIH/NINDS) [E] < (b) (6) > Gadbois, Ellen (NIH/OD) [E] < (b) (6) > Culp, Michelle (NIH/OD) [E] < (b) (6) > Jacqueline Kirchner < (b) (6) > Beigel, John (NIH) [E] < (b) (6) > Phillips, L Revell CIV DTRA RD (USA) < (b) (6) > Petrovick, Martha - 0449 - MITLL < (b) (6) > Sizemore, Christine (NIH/FIC) [E] < (b) (6) >
Cc: Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Desrosiers, Betsy < (b) (6) > Jansen, Kathrin < (b) (6) > Kurilla, Michael (NIH/NCATS) [E] < (b) (6) > Lowy, Douglas (NCI) < (b) (6) > Young, John < (b) (6) > Biggs, Mary < (b) (6) > Butcher, Tina < (b) (6) > Demarcus < (b) (6) > Macone, Erin < (b) (6) > Melencio, Cheryl (FNIH) [T] < (b) (6) > Salathin, Carla < (b) (6) > Tountas, Karen (FNIH) [T] < (b) (6) > Menetski, Joseph (FNIH) [T] < (b) (6) > James, Stephanie (FNIH) [T] < (b) (6) > Wachtel, Jonathan < (b) (6) > btolman < (b) (6) > Alvarez, Rosa Maria < (b) (6) > Gonzalez, Nina < (b) (6) > Dana Carluccio < (b) (6) > Rose Li Central Account < (b) (6) > Margaret Anderson < (b) (6) > Lucas Smalldon < (b) (6) > Stratton, Benjamin < (b) (6) > Mollica, Linda /US < (b) (6) > Qashu, Felicia (NIH/OD) [E] < (b) (6) > Patterson, Amy < (b) (6) > (NIH/NHLBI) [E] < (b) (6) > Rubin, Daniel B. (FDA/CDER) < (b) (6) > Marston, Hilary < (b) (6) > (NIH/NIAID) [E] < (b) (6) > Chen, Helen Q. < (b) (6) > Wung, Peter /US < (b) (6) > Hoots, W. Keith (NIH/NHLBI) [E] < (b) (6) > Groesch, Mary (NIH/NHLBI) [E] < (b) (6) > Shipp, Allan (NIH/NHLBI) [E] < (b) (6) > Kindzelski, Andrei (NIH/NHLBI) [E] < (b) (6) > Hone, David M (Dave) CIV DTRA J9 (USA) < (b) (6) > Reisler, Ronald B < (b) (6) >

CTR USARMY DOD JPEO CBRND (USA) < (b) (6) Freire, Maria (FNIH) [T] < (b) (6)
Elsaid, Oliv a < (b) (6) Walker, Paula (NIH/NINDS) [E] < (b) (6) Bethany Stokes
< (b) (6) asorosa < (b) (6)

Subject: Post-Acute Sequelae of COVID19 Workshop Dec 3-4

Dear ACTIV TX-Clinical WG Members,

I am reaching out to let you know that NIAID with assistance from NHLBI and other NIH ICs is planning a workshop Dec 3-4 on Post-Acute Sequelae of COVID19 (i.e. Long COVID).

The agenda is attached and the website to register is here: <https://cvent.me/MQAxOa>

Given that this meeting will occur during our normal meeting time, we will be canceling our working group meeting on December 3rd to allow all those who wish to attend this conference to do so.

If you have any questions, please do not hesitate to reach out.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) Mobile: (b) (6)
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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozette, Sam (NIH/NCATS) [E] (b) (6); Butterson, Joan (b) (6); De Claro, R. Angelo (FDA/CDER) [(b) (6); Draghia-Akli, Ruxandra [(b) (6); Gottesdiener, Keith (b) (6); Eric Hughes [(b) (6); Judy Currier (b) (6); Kim, Elizabeth [(b) (6); LaVange, Lisa [(b) (6); Mellors, John W [(b) (6); Menon, Sandeep [(b) (6); Parker, Ashley (NIH/OD) [E] (b) (6); Patel, Naimish [(b) (6); Peppercorn, Amanda (b) (6); Poole, Mike [(b) (6); Proschan, Michael (NIH/NIAID) [E] [(b) (6); Read, Sarah (NIH/NIAID) [E] [(b) (6); Santos, Michael (FNIH) [T] (b) (6); Shen, Yuan Li (FDA/CDER) [(b) (6); Stein, Peter (FDA/CDER) [(b) (6); Wholley, David (FNIH) [T] [(b) (6); Buchman, Tim (OS/ASPR/BARDA) (CTR) [(b) (6); Collins, Sylva (FDA/CDER) [(b) (6); Amanda Peppercorn [(b) (6); Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6); Koroshetz, Walter (NIH/NINDS) [E] [(b) (6); Timothy Burgess [(b) (6); Reineck, Lora (NIH/NHLBI) [E] [(b) (6); Aggarwal, Neil (NIH/NHLBI) [E] [(b) (6); Rosenberg, Yves (NIH/NHLBI) [E] [(b) (6); Goff, David (NIH/NHLBI) [E] [(b) (6)]; Brown, Jeremy (NIH/NINDS) [E] [(b) (6); Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboise]; Culp, Michelle (NIH/OD) [E] [(b) (6); Jacqueline Kirchner [(b) (6); Beigel, John (NIH) [E] (b) (6); Phillips, L Revell CIV DTRA RD (USA) [(b) (6); Petrovick, Martha - 0449 - MITLL [(b) (6); Sizemore, Christine (NIH/FIC) [E] [(b) (6); Larry Tsai [(b) (6); Levy, Elliot [(b) (6); Garner, Carl [(b) (6); Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Jansen, Kathrin [(b) (6); Lowy, Douglas (NCI) [(b) (6); Young, John [(b) (6); Biggs, Mary [(b) (6); Butcher, Tina [(b) (6); Demarcus [(b) (6); Macone, Erin [(b) (6); Melencio, Cheryl (FNIH) [T] [(b) (6); Salathin, Carla [(b) (6)]; Menetski, Joseph (FNIH) [T] [(b) (6); Dana Carluccio [(b) (6); Rose Li Central Account [(b) (6); Lucas Smalldon [(b) (6)]; [(b) (6)]; [(b) (6); Mollica, Linda /US [(b) (6); Qashu, Felicia (NIH/OD) [E] (b) (6); Patterson, Amy (NIH/NHLBI) [E] [(b) (6); Rubin, Daniel B. (FDA/CDER) [(b) (6); Marston, Hilary (NIH/NIAID) [E] [(b) (6); Chen, Helen Q. [(b) (6); Wung, Peter /US [(b) (6); Hoots, W. Keith (NIH/NHLBI) [E] [(b) (6)]; Groesch, Mary (NIH/NHLBI) [E] [(b) (6); Shipp, Allan (NIH/NHLBI) [E] [(b) (6); Kindzelski, Andrei (NIH/NHLBI) [E] [(b) (6); Hone, David M (Dave) CIV DTRA J9 (USA) [(b) (6); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA) [(b) (6); Walker, Paula (NIH/NINDS) [E] [(b) (6)]; Sorosa, Alex David [(b) (6); Lumsden, Joanne (NIH/NCATS) [C] [(b) (6); Lerner, Andrea (NIH/NIAID) [E] [(b) (6); Embry, Alan (NIH/NIAID) [E] [(b) (6); Kelly Beazley [(b) (6)]

Start: 2/11/2021 6:00:00 PM
End: 2/11/2021 7:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Bozette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Timothy Burgess; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6); Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner;

Optional Attendees: Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;
(b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Levy, Elliot
Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina;
Demarcus, Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla, Menetski, Joseph (FNIH) [T]; Dana Carluccio;
Rose Li Centra Account; Lucas SmaIdon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD)
[E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, H lary (NIH/NIAID) [E]; Chen, Helen;
Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E];
Kindzelski, Andre (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD
JPEO CBRND (USA); Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea
(NIH/NIAID) [E]; Embry, Alan (NIH/NIAID) [E]; Kelly Beazley

To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa] (b) (6) ; (b) (6) (b) (6) (b) (6) (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; (b) (6) (b) (6) (b) (6) (b) (6) Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; (b) (6) (b) (6) (b) (6) : Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; (b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas (b) (6) ; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar (b) (6) ; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) (b) (6) Puntunieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-puntunieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6) (b) (6)

CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Hughes, Eric (b) (6) Jansen, Kathryn (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria (b) (6) Kim, Elizabeth (b) (6) Tolman, Brett (b) (6) Wachtel, Jonathan (b) (6) Prabhavathi Fernandes (b) (6) Rose Li (b) (6) Dana Carluccio (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Simon, Dina (NIH/OD) [C]

[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
(NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
| (b) (6) Dave Frankowski | (b) (6) Baric, Toni C
| (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin
| (b) (6) Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Diamond, Michael
(b) (6)]; Gonzalez, Nina | (b) (6)

Start: 6/10/2020 2:00:00 PM

End: 6/10/2020 3:00:00 PM

Recurrence: (none)

From: Connelly, Sarah | (b) (6)
Sent: 12/2/2020 12:15:54 AM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp];
(b) (6) Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) jrappaport@tulane.edu; ka (b) (6) jay (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6)]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6)]; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6)]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbbc2fed349-lumsdenjm]; KCLloyd@ucdavis.edu
CC: Diamond, Michael | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Alvarez, Rosa Maria

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Kim, Elizabeth [(b) (6) btolman [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Wachtel, Jonathan (b) (6) Prabhavathi Fernandes [(b) (6) Rose Li [(b) (6) Dana Carluccio [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D [(b) (6) Dave Frankowski [(b) (6) antoinette_baric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Mason, Stephen (b) (6)

Subject: RE: ACTIV Preclinical full working group

Attachments: ACTIV_Preclinical_Viral Mutation and Prediction of Escape_12012020_v1.pptx

Hi All,

Apologies for the multiple emails, ahead of our meeting tomorrow, the preclinical team has refined the slides that will guide our discussion on ongoing viral sequence tracking and testing efforts (attached).

Prior to our meeting, **please take a moment to review these topics** and be ready to share any thoughts you may have. We look forward to continuing the discussions and appreciate the time and effort you all have put towards this subject to date.

Best regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: (b) (6)
www.deloitte.com

From: Connelly, Sarah

Sent: Tuesday, December 1, 2020 4:12 PM

To: Menetski, Joseph (FNIH) [T] < (b) (6) (b) (6) Hild, Sheri (NIH/OD) [E]

< (b) (6) (b) (6) (b) (6) j (b) (6)

(b) (6) (b) (6) (b) (6) Baric, Ralph < (b) (6)

(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] < (b) (6) Colvis, Christine

(NIH/NCATS) [E] < (b) (6) Hewitt, Judith (NIH/NIAID) [E] < (b) (6) Deming, Damon

(FDA/CDER) < (b) (6) (b) (6) (b) (6) (b) (6)

Parker, Ashley (NIH/OD) [E] < (b) (6) Collins, Francis (NIH/OD) [E] < (b) (6)
 < (b) (6) Adams, Peter (OS/ASPR/BARDA) < (b) (6) Rao, Srinivas
 < (b) (6) Qashu, Felicia (NIH/OD) [E] < (b) (6) Tomas Cihlar
 Punturieri, Antonello (NIH/NHLBI) [E] < (b) (6) Charette, Marc (NIH/NHLBI) [E]
 < (b) (6) Fessel, Josh (NIH/NHLBI) [E] < (b) (6) (b) (6) Lumsden,
 Joanne (NIH/NCATS) [C] < (b) (6) (b) (6)
 CC: Diamond, Michael < (b) (6) Wholley, David (FNIH) [T] < (b) (6) Austin, Christopher
 (NIH/NCATS) [E] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6) Desrosiers, Betsy
 < (b) (6) Eric Hughes < (b) (6) Jansen, Kathrin
 < (b) (6) Kurilla, Michael (NIH/NCATS) [E] < (b) (6) Lowy, Douglas (NCI)
 < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6)
 Santos, Michael (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] < (b) (6) James, Stephanie (FNIH)
 [T] < (b) (6) Alvarez, Rosa Maria < (b) (6) Kim, Elizabeth < (b) (6) Tolman,
 Brett < (b) (6) Wachtel, Jonathan < (b) (6) Prabhavathi Fernandes
 < (b) (6) Rose Li < (b) (6) Dana Carluccio
 < (b) (6) Lagos, Enrique (NIH/NCATS) [E] < (b) (6) Jonson, Samantha
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 < (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] < (b) (6) Rodriguez, Robin D
 < (b) (6) Dave Frankowski < (b) (6) Baric, Toni C
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 < (b) (6) Nancy Haigwood < (b) (6) Stratton, Benjamin < (b) (6)
 Gadbois, Ellen (NIH/OD) [E] < (b) (6) Anderson, James (NIH/OD) [E] < (b) (6)
 Hawk, Harrison < (b) (6) Mason, Stephen < (b) (6)
 (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group Members,

Please see below for the agenda for tomorrow's meeting at 10:00 AM ET. If you have any questions or items to add, please let us know.

Agenda Topic	Duration	Facilitator
Preclinical WG Strategic Objectives - Updates	20 mins	Joe Menetski John Young Christine Coivis
Discuss Viral Mutation and Prediction of Escape	20 mins	Joe Menetski John Young Christine Coivis
Discuss Subgroup updates <ul style="list-style-type: none"> o Preclinical prioritization o In vivo strategy <ul style="list-style-type: none"> o Field Guides o Viral Stocks o Data portal implementation 	10 mins	John Young Nancy Haigwood Cat Lutz Isis Kanevsky Clint Florence Sam Jonson
Discuss Small Animal Models and NHP Field Guides	10 mins	Nancy Haigwood Cat Lutz Isis Kanevsky

Looking forward to talking to everyone tomorrow!

All the best,
Sarah

Sarah Connelly, PhD
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-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] (b) (6)

Sent: Tuesday, April 14, 2020 6:43 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E]; (b) (6) (b) (6)

(b) (6)
(b) (6) Baric, Ralph; (b) (6); Ottinger, Elizabeth (NIH/NCATS [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon (FDA/CDER); (b) (6); Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E]; Fessel, Josh (NIH/NHLBI) [E]; (b) (6)
Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Eric Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim, Elizabeth, Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Rose Li; Dana Carluccio; Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; Baric, Toni C; Lowy, Douglas (NIH/NCI) [E]; Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Hawk, Harrison; Diamond, Michael; Mason, Stephen;

(b) (6) Connelly, Sarah

Subject: ACTIV Preclinical full working group

When: Wednesday, November 11, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/> (b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/13/2020 7:23:25 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesd ener, Ke.th
(b) (6) Hughes, Eric | (b) (6) Judy Currier
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras], Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Ste n, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
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Subject: Follow-up from 1st Meeting of COVID PPP Therapeutics-Clinical Working Group - RAPID RESPONSE REQUESTED
Attachments: berlin definition.pdf, gattinoni.pdf; ARDS history.pdf; ashbaugh and petty.pdf; Tenney Remers.pdf

Dear ACTIV Therapeutics-Clinical WG,

Thank you all for a very productive discussion today. We appreciate all of you taking the time to join the meeting.

As discussed on the call today, I am reaching out to ask for volunteers for each of the two main sub-groups for our WG:

1. Agent Prioritization Process, Criteria, and Initial Agent List
2. Development of COVID Master Protocols

Please send me your availability to participate and your preference for which sub-group you would like to join. In addition, please send your preferred time windows or any restricted times over the next two days. Please send me this information by no later than 10 pm US ET today if you can. This will allow us to plan the meetings rapidly for Tuesday and Wednesday.

We will be working to get together agendas and will share them as they come together.

In addition to sending the information above, Tim Buchman from BARDA asked me to share the attached materials and the thoughts below for consideration on our use of the ARDS terminology.

A Remark on Terminology: "ARDS" as an expression of COVID-19

Contemporary respiratory distress syndromes were unknown until the 1960s. Prior to the invention and diffusion of mechanical ventilators following the polio epidemics of the 1950s, patients simply succumbed to severe pneumonia.

In 1967, David Ashbaugh, Tom Petty and others reported a case series of a dozen patients who experienced severe respiratory illness with chest radiographs similar to what would be observed in congestive heart failure but without the heart failure (pdf attached). The lungs simply leaked fluid.

The history of that report is summarized by Levine (one of the authors of the 1967 report) and is also attached

Pertinent to the next half century of ARDS are the following:

- (a) "ARDS" was recognized as a final common pathway to diverse insults including (but not limited to) trauma, pancreatitis, pneumonia, and anatomically distant sepsis;*
- (b) development of a standard supportive strategy namely "lung protective, low-tidal volume ventilation" that emerged from ARDSNET (see <https://www.nejm.org/doi/full/10.1056/NEJM200005043421801>) but in fact simply reflected normal tidal volumes across all mammals, see figure 1 in the Tenney and Remmers 1963 paper, pdf attached.*
- (c) a contemporary definition of ARDS that focuses almost exclusively on the extent of hypoxemia without attention to the defect in diffusion of oxygen across the alveolar-capillary membrane (the Berlin criteria, pdf attached).*

Thus until 2020, ARDS accumulated underlying pathogenesises. As a consequence, treatment focused on "greatest good for greatest number" Whilst address of the underlying cause has always been part of ARDS treatment, the ventilator support regimen has been largely "one size fits most".

SARS-CoV-2 has changed the landscape. A single pathogen has affected populations of diverse heritable and acquired underlying pulmonary conditions. The pathophysiologic responses to the pathogen are partitioning into several endotypes. This has prompted both experts and pundits to call for a revision of the "one size fits most" into more tailored approaches. See the Gattinoni pdf published a couple of weeks ago in the ATS journal (pdf attached.)

There is a manuscript from John Marini and Gattinoni that will run in one of the journals I edit in the near future focusing on how ventilators injure vulnerable lungs. Luciano Gattinoni has separately contacted one of my Associate Editors to write a piece for the other journal that I edit. Suffice it to say that the conversation about partitioning treatment into approaches that reflect the expression of COVID-19 could well be part of the presentation.

I share all of the above information simply to highlight the fact that convolving the pulmonary injury consequent to SARS-CoV-2 with the term "ARDS" brings a half-century of knowledge—and also of baggage—to the therapeutics

conversation. Perhaps we should be as careful and specific in the terms we choose to describe the pulmonary injury as we should be in testing candidate therapies.

Our choice of words, like our choice of drugs, matters.

Tim

Timothy G. Buchman, PhD, MD

Senior Advisor

IPA to the DRiVe (Division of Research, Innovation and Ventures)

Biomedical Advanced Research and Development Authority (BARDA)

Office of Assistant Secretary for Preparedness and Response (ASPR)

U.S. Department of Health and Human Services (HHS)

Thank you all in advance for your timely responses.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

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From: Plenge, Robert [REDACTED] (b) (6)
Sent: 7/29/2020 11:33:01 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data ([here](#), [here](#), [here](#), [here](#)), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

From: "Melencio, Cheryl (FNIH) [T]" <[REDACTED] (b) (6)> on behalf of "Wholley, David (FNIH) [T]" <[REDACTED] (b) (6)>
Date: Tuesday, July 28, 2020 at 10:55 PM
To: "Austin, Christopher (NIH/NCATS) [E]" <[REDACTED] (b) (6)> "Bancel, Stephane" <[REDACTED] (b) (6)>
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< (b) (6) "Koob, George (NIH/NIAAA) [E]" < (b) (6) "Koroshetz, Walter
 (NIH/NINDS) [E]" < (b) (6) "Langevin, Helene (NIH/NCCIH) [E]"
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 "Tumminia, Santa (NIH/NEI) [E]" < (b) (6) "Volkow, Nora (NIH/NIDA) [E]"
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 "Burklow, John (NIH/OD) [E]" < (b) (6) "Castillejos, Carlos" < (b) (6) "Culp,
 Michelle (NIH/OD) [E]" < (b) (6) FNIH Central Account < (b) (6) "Freire,
 Maria (FNIH) [T]" < (b) (6) "Gadbois, Ellen (NIH/OD) [E]" < (b) (6) "Wolinetz,
 Carrie (NIH/OD) [E]" < (b) (6) "Burklow, John (NIH/OD) [E]" < (b) (6)
 "Gorman, Greta (FNIH) [T]" < (b) (6) "Hallett, Adrienne (NIH/OD) [E]"
 < (b) (6) "Meltzer, Abbey (FNIH) [T]" < (b) (6) "Myles, Renate (NIH/OD) [E]"
 < (b) (6) "Melencio, Cheryl (FNIH) [T]" < (b) (6)

Subject: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Resent-From: < (b) (6) >

[Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

Join Zoom Meeting

<https://fnih.zoom.us/>

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Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-ME.LENCIOC]

Sent: 8/18/2020 2:53:18 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6)]; Collins, Francis (NIH/OD) [E] [(b) (6) Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6)]; Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeiding, Emily (NIH/NIAID) [E] [(b) (6) Erck, Stan [(b) (6)]; Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6)]; Marston, Hilary (NIH/NIAID) [E] [(b) (6)]; Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Pandya, Hitesh [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Rachel Ramoni [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6) Talley, Michael [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6)]; Hallett, Adrienne (NIH/OD) [E] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6) Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Bugin, Kevin (FDA/CDER) [(b) (6) Bancel, Stephane [(b) (6)]; Fauci, Anthony (NIH/NIAID) [E] [(b) (6) Lepore, John [(b) (6) Pangalos, Mene [(b) (6) Paul, Steve [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6)]; Tsai, John [(b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet Woodc]

CC: Austin, Sarah (NIH/NIAID) [E] [(b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Bell, Julie [(b) (6) Caulfield, Anita [(b) (6)]; Coan, Amanda [(b) (6)]; Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Ilerdemaj, Vaide [(b) (6) Jenkins, Christine S. [(b) (6) Lever, Susan [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6) Riffin, Mary [(b) (6) Ripley, Nadege [(b) (6) Schuster, Donna [(b) (6) Suhana, Tina (NIH/VRC) [E] [(b) (6) Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Togashi, Mieko (NIH/NCI) [E] [(b) (6) Underwood, Nancy [(b) (6) Zottoli, Jessica [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Carver, Treia (NIH) [C] [(b) (6) Hughes, Karen (NIH/OD) [E] [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6) Sepulveda, Donna (FNIH) [T] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Tajalli, Ada (NIH/OD) [E] [(b) (6)]; Gorman, Greta (FNIH) [T] [(b) (6)

Meltzer, Abbey (FNIH) [T]	(b) (6)	Regan, Donna M	(b) (6)	Lucas Smalldon
(b) (6)		Alvarez, Rosa Maria	(b) (6)	Gonzalez, Nina
(b) (6)	Appell, Evan	(b) (6)	Adam, Stacey (FNIH) [T]	(b) (6)
Anderson, Margaret	(b) (6)	Chen, Helen Q.	(b) (6)	Hawk, Harrison
(b) (6)	Stratton, Benjamin	(b) (6)	Tolman	(b) (6) Tountas,
Karen (FNIH) [T]	(b) (6)	Wachtel, Jonathan	(b) (6)	Dana Carluccio
(b) (6)		Lowy, Douglas (NIH/NCI) [E]	(b) (6)	John Lepore
(b) (6)	Huang, Grant	(b) (6)	Hamilton, Nancy	
(b) (6)	Elsaid, Olivia	(b) (6)		

Subject: ACTIV Leadership Call #8

Location: <https://fnih.zoom.us> (b) (6)

Start: 9/23/2020 1:00:00 PM

End: 9/23/2020 2:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Ras, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholey, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy, Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Bugin, Kevin (FDA/CDER)

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Mennich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Enrique (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Regan, Donna M; Hamilton, Nancy; Lucas Smalldon; Alvarez, Rosa Maria; Gonzalez, Nina; Appell, Evan; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Hawk, Harrison; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Dana Carluccio; Lowy, Douglas (NIH/NCI) [E]; John Lepore; Huang, Grant

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 4:45:30 PM
To: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Hi Gretchen and Cheryl,

Dr. Carrie Wolinetz would like to join this meeting. Cheryl – should I forward the invite or would you prefer to add on your end?

Thank you,
Ashley

From: Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 11, 2020 9:23 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)> Fauci, Anthony (NIH/NIAID) [E] <(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Stoffels, Paul <PSI (b) (6)> Pao, William <(b) (6)> Dolsten, Mikael <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Desrosiers, Betsy <(b) (6)> Hughes, Eric <(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E] <(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Young, John <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: Re: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Good morning,

Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation will be shared with you soon.

With very best wishes,

Gretchen

From: Francis Collins <(b) (6)>
Date: Saturday, May 9, 2020 at 1:07 PM
To: Francis Collins <(b) (6)> >, Anthony Fauci <(b) (6)> "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)> , " (b) (6) <(b) (6)> Gretchen Wood <(b) (6)> "Pao, William" <(b) (6)> , " (b) (6) <(b) (6)> >, "Colvis, Christine (NIH/NCATS) [E]" <(b) (6)> , "Desrosiers,

Betsy" (b) (6) "Hughes, Eric" < (b) (6) "Jansen, Kathrin"
 (b) "Kurilla, Michael (NIH/NCATS) [E]" (b) (6) , "Lowy, Douglas
 (NCI)" < (b) (6) "Read, Sarah (NIH/NIAID) [E]" < (b) (6) "Young, John"
 (b) (6)
 Cc: David Wholley < (b) (6) "Menetski, Joseph (FNIH) [T]" (b) (6) , "Adam, Stacey
 (FNIH) [T]" < (b) (6) "Tountas, Karen (FNIH) [T]" < (b) (6) "Santos, Michael (FNIH) [T]"
 < (b) (6) Maria Freire < (b) (6) "Tabak, Lawrence (NIH/OD) [E]"
 < (b) (6) "Lane, Cliff (NIH/NIAID) [E]" < (b) (6) , Ashley Parker
 < (b) (6) James Anderson < (b) (6) "Austin, Christopher (NIH/NCATS)
 [E]" < (b) (6) , "Melencio, Cheryl (FNIH) [T]" < (b) (6) >, Gretchen Wood
 < (b) (6)

Subject: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Dear ACTIV Executive Committee Members and Working Group Co-Chairs:

Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together. There are also concerns about how we should best communicate across our partnership and coordinate with the many parallel (and in some cases conflicting) efforts that have emerged elsewhere—including among our own ACTIV members.

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/28/2020 8:32:48 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]
Subject: ACTIV Therapeutics-Clinical Agent Prioritizat on Subgroup Meeting #5
Location: <https://fnih.zoom.us>, (b) (6)
Start: 4/30/2020 7:00:00 PM
End: 4/30/2020 8:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes; Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon

Dear TX-Clinical APSG,

I had my days incorrect. This meeting was supposed to be tomorrow (Wednesday). I don't think this is the right timing, so I am moving it to Thursday and scheduling another call on Friday per our discussion.

Thanks,

Stacey

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/23/2020 5:17:02 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan (b) (6) Judy Currier (b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Karen Lynn Price [(b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [(b) (6) Woodcock, Janet (FDA/CDER) (b) (6) Stein, Peter (FDA/CDER) [(b) (6) Carlos O Garner [(b) (6) Bugin, Kevin (FDA/CDER) [(b) (6) Marks, Gilbert (OS/ASPR/BARDA) (CTR) (b) (6) Farley, John (FDA/CDER) (b) (6) Jens Lundgren (b) (6) Demarcus [(b) (6)]; Tountas, Karen (FNIH) [T] [(b) (6) Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Chen, Helen Q. [(b) (6) Salathin, Carla [(b) (6)

Subject: ACTIV mAb Steering Committee Meeting
Attachments: ACTIV TX-Clinical mAb Steering Committee Meeting_20200529.pdf
Location: <https://fnih.zoom.us/>, (b) (6)

Start: 5/29/2020 6:00:00 PM
End: 5/29/2020 7:00:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Judy Currier; Eric Hughes; Lisa LaVange; Read, Sarah (NIH/NIAID) [E]; Karen Lynn Price; Higgs, Elizabeth (NIH/NIAID) [E]; Woodcock, Janet (FDA/CDER); Stein, Peter (FDA/CDER); Carlos O Garner; Bugin, Kevin; Marks, Gilbert (OS/ASPR/BARDA) (CTR); Farley, John (FDA/CDER); Jens Lundgren
Optional Attendees: Demarcus; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Chen, Helen Q.; Salathin, Carla

Dear mAb Steering Committee,

Please find attached the proposed agenda and slides for tomorrow. Please let us know if we need to add anything else to the agenda.

Thanks,
Stacey

Join Zoom Meeting
<https://fnih.zoom.us/j/9181151111> (b) (6)

Meeting ID: (b) (6)
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US (San Jose)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://fnih.zoom.us/> (b) (6)

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/17/2020 1:11:38 PM
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(b) (6); (b) (6); (b) (6); (b) (6)
(b) (6); (b) (6); (b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcb42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6); (b) (6); (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Srinivas.Rao@sanofi.com; Alvarez, Rosa Maria [(b) (6)
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6)]; Hughes, Eric [(b) (6)] Jansen, Kathrin [(b) (6)] Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Kim, Elizabeth [(b) (6)] Tolman, Brett [(b) (6)] Wachtel, Jonathan [(b) (6)] Prabhavathi Fernandes [(b) (6)] Diamond, Michael [(b) (6)] Rose Li [(b) (6)] [(b) (6)] Dana Carluccio [(b) (6)] Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]
Subject: RE: COVID Preclinical Working group Meeting #2
Attachments: PRECLINICAL Working Group FNIH_Meeting 2_0417_vF4.pdf; 20200416_PRECLINICAL Working Group_Animal Models_Actions and observations_d3.docx; Inventory Template columns for WG review_4 16 2020.xlsx; In vitro Subteam notes and actions 4 16 d4.docx

Hi all,

Please find attached a few materials for our discussion today:

1. Slides for our discussion today
2. Notes from the Animal Model Subgroup
3. Notes from the In Vitro Assay Subgroup
4. Framework for the preclinical data inventory (including data fields for the Preclinical compound list, Animal Model list, In vitro Assay List and BSL 3/4 Facilities List)

Please let us know if you have any modifications to the data fields to be included in the inventory

For logistic purposes, if you plan to call into the meeting with phone only, could you please send me your telephone number prior to the meeting. Having you number will allow me to keep track of who is attending the meetings.

Looking forward to our discussion at 11am ET.

Sincerely,

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] (b) (6)
Sent: Sunday, April 12, 2020 12:50 PM
To: Menetski, Joseph (FNIH) [T]; (b) (6) kara. (b) (6)
Annaliesa.Anderson@pfizer.com; (b) (6) Baric, Ralph; (b) (6) Ottinger, Elizabeth
(NIH/NCATS) [E] Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; Deming, Damon
(FDA/CDER); (b) (6) (b) (6) Parker, Ashley (NIH/OD)
[E]; (b) (6) Adams, Peter (OS/ASPR/BARDA); Jonson, Samantha (NIH/NCATS) [E]
Cc: Collins, Francis (NIH/OD) [E]; Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E];
Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael
(NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas, Karen (FNIH) [T]; Santos,
Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria; Kim,
Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana
Carluccio; Lagos, Enrique (NIH/NCATS) [E]
Subject: COVID Preclinical Working group Meeting #2
When: Friday, April 17, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://zoom.us> (b) (6)

Saving time on the calendar.

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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US (Houston)

Meeting ID: (b) (6)

Password: (b) (6)

Find your local number: <https://zoom.us/> (b) (6) <<https://zoom.us/> (b) (6)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/19/2020 6:39:15 PM
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CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: FW: URGENT: Invitation to join the ACTIV Vaccines Working Group

FYI we have heard back from Stephane Bancel: Moderna will be sending their CMO, Tal Zaks (who is leading CoV2 vaccine development), to join the Vaccines call tomorrow. He's been sent the invite and has acknowledged receipt. Thanks for your help, Francis.

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 10/16/2020 8:50:45 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collins]
Subject: FW: 1st ACTIV-1 patient has been randomized
Flag: Follow up

Francis,
Thought you'd enjoy seeing this, came to me just as our Livestream ended.
And note it's WashU, where the trial PI (Bill Powderly) is, in case that's useful for Mr. Blunt.
Chris

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>
Sent: Friday, October 16, 2020 4:48 PM
To: Boucher, Cynthia (NIH/NCATS) [E] <(b) (6)> Atkinson, Jane (NIH/NCATS) [E]
<(b) (6)> Chang, Soju (NIH/NCATS) [E] <(b) (6)> ' (b) (6)
<(b) (6)> 'Gavin, Brian' <(b) (6)> 'Sadeh, Jonathan' <(b) (6)
'Melsheimer, Rich [CNTNL]' <(b) (6)> 'Beumont-Mauviel, Maria [JRDUS]' <(b) (6)
'Bharucha_David' <(b) (6)> 'Ferguson_William' <(b) (6)> Eric Hughes
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<(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> 'Kimmel, Bridget [JRDUS
<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Marti, Emily (NIH/NCATS) [E]
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<(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Collins, Francis (NIH/OD) [E]
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<(b) (6)
Cc: 'Montgomery, Stephanie' <(b) (6)> O'Sullivan_Alexandra
<(b) (6)> Stock, Thomas (HHS/IOS) <(b) (6)> Neta Nelson
<(b) (6)> Butler, Sandy <(b) (6)> Daniel Benjamin Jr, M.D., Ph.D.
<(b) (6)> Theresa Jasion <(b) (6)> Molina, Daniel <(b) (6)
Rose Beci <(b) (6)> Lind, Brian (NIH/NCATS) [E] <(b) (6)> Mason, Robin (OS/ASPR/BARDA)
<(b) (6)> O'rourke, Anna (OS/ASPR/BARDA) (CTR) <Anna (b) (6)> Austin, Christopher
(NIH/NCATS) [E] <(b) (6)> Lori Hudson, Ph.D. <(b) (6)> "Huyen Cao"
<(b) (6)> <"Huyen Cao" <(b) (6)> Huyen Cao <(b) (6)> Brody, Betty
(OS/ASPR/BARDA) <(b) (6)> Chiang, Anna (OS/ASPR/BARDA) <(b) (6)> Schmidt, Jeffrey
(OS/ASPR/BARDA) <(b) (6)
Subject: 1st ACTIV-1 patient has been randomized

Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all!
Sam B

Sam Bozzette, MD, PhD
Chief Medical Officer

*Immediate Office of the Director
National Center for Advancing Translational Sciences
National Institutes of Health*

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Bethesda, MD 20892

(Use ZIP code 20817 for overnight mail or courier)

Phone: (b) (6)

E-mail: (b) (6)

NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 10/20/2020 8:55:08 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV Leadership Team Meeting October 21, 2020

Slight typo in the salutation calling this the AMP Leadership Team. Made me wonder where I was for a minute. ☺

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, October 20, 2020 4:34 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling, Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E]
<(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas
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Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary
(NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David
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(CDC/DDID/NCIRD/OD) <(b) (6)> Pandya, Hitesh <(b) (6)> Pangalos, Mene
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Plenge, Robert <(b) (6)> Plump, Andy <(b) (6)> Rachel Ramoni
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<(b) (6)> Rouse, Doris <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Skovronsky, Daniel <(b) (6)>
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Young, John <(b) (6)> Victoria Davey <(b) (6)> Austin, Christopher (NIH/NCATS) [E]
Cc: Anderson, James (NIH/OD) [E] <(b) (6)> Carluccio, Dana
<(b) (6)> Burklow, John (NIH/OD) [E] <(b) (6)> Culp, Michelle (NIH/OD) [E]
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<(b) (6)> FNIH Central Account <(b) (6)> Parker, Ashley (NIH/OD) [E]
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<(b) (6)> Mendelson, Jesse <(b) (6)> asorosa <(b) (6)> Stratton,
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Benjamin < (b) (6) btolman < (b) (6) Tountas, Karen (FNIH) [T]
< (b) (6) Wachtel, Jonathan < (b) (6) Wholley, David (FNIH) [T] < (b) (6)

Subject: ACTIV Leadership Team Meeting October 21, 2020

Importance: High

Dear AMP Leadership Team and meeting attendees:

Attached please find the slides for our meeting **tomorrow morning, Wednesday October 21, from 9:15 – 10:15 AM Eastern U.S. Time.** We will be focusing a good part of the call on trial accrual challenges discussed during our ACTIV Executive Committee call on October 7. The minutes from that meeting as well as those from our last Leadership Team call on September 23 are also attached to this note.

The logistics for the Zoom call, which were previously sent to you in the Outlook calendar invitation, are as follows:

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United Kingdom

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom>, (b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

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In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 2/13/2021 4:17:15 PM
To: (b) (6)
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Barasch, Kimberly (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]
Subject: RE: [EXTERNAL] a few follow ups

Hi (b) (6)

I've discussed with Tony, and we are very interested in meeting with you and your team. I'd like Tony, Cliff Lane, David Wholley, and me to join, and you can decide which of the Pfizer team would be most essential.

I'm looping in Gretchen Wood who can work with your Pfizer team to find a good time for this. Tuesday may be a challenge, but all of us will seek to move calendars around if necessary.

Best, Francis

From: (b) (6)
Sent: Friday, February 12, 2021 2:32 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Subject: Re: [EXTERNAL] a few follow ups

Francis

If you prefer a smaller group, I am pleased also to present the protease drug highlights myself and join together with our CEO Albert Bourla from Pfizer to meet the three of you

Best (b) (6)

Sent from my iPhone

On Feb 12, 2021, at 14:16, (b) (6) > wrote:

Dear Francis

I and our Pfizer CEO Albert Bourla just reviewed the clinical plans from our protease inhibitor team. We also assessed manufacturing needs (for EUA) to possibly plan for success with time lines for potential EUA already in 2021 or early 2022 (pending good data of course).

We would enjoy as you suggested below meeting you , Tony and David as soon as possible - maybe Tuesday next week (Monday is holiday) to discuss how we can work together on our IV and ORAL pan-Corona virus protease inhibitor (PI) drugs .

in this time of SARSCov2 viral evolution , they seems like a drug class w great promise .

We have submitted the IV PI drug to ACTIV w positive reception . We are planning to submit the oral PI drug to ACTIV on Wednesday next week .

Albert will join me in the meeting w you. If you want to have some more detailed background science on the drugs , I was think ng to bring in our two key scientist leaders in this area eg Liesa Anderson and Charlotte Allerton . Liesa participated in ACTIV since the start within therapeutics related work streams

Look forward to your response

Best

(b) (6)

Sent from my iPhone

On Feb 11, 2021, at 05:26, Collins, Francis (NIH/OD) [E] (b) (6) wrote:

Hi (b) (6)

Thanks for quick response to my message – and wow, the progress on the oral anti-protease is fantastic! In the face of rising concerns about viral variants in the spike protein, the efficacy against all coronaviruses is extremely encouraging – will this even cure the common cold? 😊 I am sure the ACTIV team would be ready to move quickly to slot this into ACTIV-2/3, pending the results of your phase 1 SAD-MAD studies. Considering possible combination therapies could also be a very appealing next step.

Let me know when you are ready to discuss – I'd like to bring Tony Fauci and David Wholley into that conversation soon.

Best, Francis

From: (b) (6)
Sent: Wednesday, February 10, 2021 8:36 AM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Subject: Re: [EXTERNAL] a few follow ups

Hi Francis

Good that you try to correct NYT article but TIME paper was great

The exciting piece w the antiviral protease inhibitor (PI) drugs is that they are pan-corona virus active w potential as a drug for any new pandemic coronavirus. They also wil inhibit all presently known SARSCov2 mutant variants that mainly affect SPIKE

Confidential update

(b) (4)

Mikael

Sent from my iPhone

On Feb 10, 2021, at 06:33, Collins, Francis (NIH/OD) [E]

(b) (6) wrote:

Hi (b) (6)

Just checking in. First, thanks for your kind words that were quoted in the TIME magazine profile – very much appreciated!

Second, I have been distressed by the uninformed characterization of the ACTIV efforts on therapeutics in the New York Times article ten days ago by Carl Zimmer, and a more recent OpEd from Zeke Emanuel et al. The TIME article gave a much more accurate depiction, and I hope that was noticed. My staff and I are working in other ways to correct the record on this – including an upcoming New Yorker article and 60 Minutes segment that will be much more positive!

Third, I am glad to see positive momentum in moving forward with the Pfizer anti-protease therapeutic through ACTIV. I hear good things

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about PF-07304814, and the potential for entering this into the ACTIV-3 trial in the near future. Of course I'm also intensely curious about your progress with an oral anti-protease, since that could be a true game-changer for this pandemic – and an advance desperately needed at a time where new SARS-CoV-2 viral variants are causing a lot of concern. Anything you can tell me about progress there?

All the best, Francis

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 7/23/2020 8:28:22 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Bascles, Lionel [(b) (6) Cohen, Myron [(b) (6) Corey, Larry [(b) (6) Victoria Davey [(b) (6) Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [(b) (6) Doroshow, James (NIH/NCI) [E] [(b) (6) Garner, Carlos [(b) (6) Goff, David (NIH/NHLBI) [E] [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Mensah, George (NIH/NHLBI) [E] [(b) (6) Nayak, Seema (NIH/NIAID) [E] [(b) (6) Payton, Manizhe (NIH/NIAID) [E] [(b) (6) Resnansky, Laura [resnansky. (b) (6) Sizemore, Christine (NIH/FIC) [E] [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Takas, Therese [(b) (6) Vincent, Mike [(b) (6) Weinmann, Gail (NIH/NHLBI) [E] [(b) (6) Srinivasan, Badhri [(b) (6)]
CC: Wachtel, Jonathan [(b) (6)], Colvis, Christine (NIH/NCATS) [E] [(b) (6) Eric Hughes [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Young, John [(b) (6) Ardiffe, Bernadette [(b) (6) Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Minnich, Beth [(b) (6) Mueller-Reichenstein, Petra [(b) (6) Pico, Dianna (NIH/NHLBI) [C] [(b) (6) Quadros, Nora [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [(b) (6)]; Hill, Zoe (NIH/NHLBI) [C] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Anderson, Margaret [(b) (6)]; Parker, Ashley (NIH/OD) [E] [(b) (6)]; Carluccio, Dana [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gonzalez, Nina [(b) (6) Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Kenny, Dermot [(b) (6) Kublin, James [(b) (6) : Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Tuveson, Nancy [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Bethany Stokes [(b) (6) Collins, Francis (NIH/OD) [E] [(b) (6)] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [(b) (6)]
Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda 07282020 pdf
Location: https://fnih.zoom. (b) (6)
Start: 7/28/2020 1:00:00 PM
End: 7/28/2020 2:00:00 PM
Show Time As: Tentative

Required Attendees: Bascles, Lionel; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshow, James (NIH/NCI) [E]; Garner, Carlos; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Mensah, George; Nayak, Seema (NIH/NIAID) [E]; Payton, Manizhe; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Takas, Therese; Vincent, Mike; Weinmann, Gail
Optional Attendees: Wachtel, Jonathan; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Ardiffe, Bernadette; Criffield, Robin; Hamilton, Nancy; Melencio, Cheryl (FNIH) [T]; Minnich, Beth; Mueller-Reichenstein, Petra; Pico, Dianna; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] [(b) (6) Zoe (NIH/NHLBI) Hill [C] [(b) (6) Adam, Stacey (FNIH) [T], Anderson, Margaret; Ashley (NIH/OD) Parker [E] [(b) (6) Carluccio, Dana; Culp Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Gonzalez, Nina; Heaton, Penny; James, Stephanie; Kenny, Dermot; Kublin, James; Li, Rose; Menetski, Joseph (FNIH) [T], Qashu, Felicia; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Bethany Stokes; Collins, Francis (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]

Dear Colleagues, Attached, please find the agenda for this last meeting of the Clinical Trial Capacity Working Group. With best regards, Karen

Dear Clinical Trial Capacity Working group members - As the tiger teams continue to work closely with ACTIV protocol development and operations teams, and the 'playbook' development teams ramp up to quickly develop these resources, we will reduce the number of times the full WG meets in July to every other week (July 14th and 28th). Best, Karen

Karen Tountas is inviting you to a scheduled Zoom meeting.

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 Jonathan (b) (6)]; Prabhavathi Fernandes [(b) (6) Rose Li
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| (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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| (b) (6) Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]

Start: 7/8/2020 2:00:00 PM
End: 7/8/2020 3:00:00 PM

Recurrence: (none)

From: Florence, Clint (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E032D0BC8554E8787E844A7773295FE-FLORENCEWC]
Sent: 1/21/2021 6:34:14 PM
To: Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email];
(b) (6) Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbcd42cbb4014d9b26af30cc-jhewitt]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda];
(b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkera]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf];
(b) (6) Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Rao, Srinivas [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Tomas Cihlar [(b) (6) Pitt, Margaret L CIV USARMY MEDCOM USAMRIID (USA) [(b) (6) Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; (b) (6)
(b) (6)
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Desrosiers, Betsy [(b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Ames, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Prabhavathi Fernandes
 | (b) (6) Diamond, Michael | (b) (6) Rose Li
 | (b) (6) Dana Carluccio | (b) (6) Lagos, Enrique (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Jonson, Samantha
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Rodriguez, Robin D
 | (b) (6) Dave Frankowski | (b) (6) antoinette_baric
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userb6b844cf]; Lowy,
 Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nancy Haigwood
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Gadbois, Ellen
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Anderson, James
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8];
 Mason, Stephen [Stephen. (b) (6)]; caroline (b) (6) (b) (6)
 Lumsden, Joanne (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; K C Kent Loyd
 | (b) (6) (b) (6)

Subject: RE: ACTIV Preclinical full working group

Hello All –

(b) (4)

Thanks --

Clint

From: Connelly, Sarah <(b) (6)>
Sent: Thursday, January 21, 2021 1:19 PM
To: Menetski, Joseph (FNIH) [T] <(b) (6)> Hild, Sheri (NIH/OD) [E] <(b) (6)>
david. <(b) (6)> Baric, Ralph <(b) (6)> john. <(b) (6)> Ottinger,
(b) (6) Elizabeth (NIH/NCATS) [E] <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)>
Hewitt, Judith (NIH/NIAID) [E] <(b) (6)> Deming, Damon (FDA/CDER) <(b) (6)>
(b) (6) Cat. <(b) (6)> Parker, Ashley (NIH/OD) [E]
<(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Adams, Peter (OS/ASPR/BARDA) <(b) (6)> Rao, Srinivas <(b) (6)> Qashu, Felicia
(NIH/OD) [E] <(b) (6)> Tomas Cihlar <(b) (6)> Pitt, Margaret L CIV USARMY
MEDCOM USAMRIID (USA) <(b) (6)> Punturieri, Antonello (NIH/NHLBI) [E]
<(b) (6)> Charette, Marc (NIH/NHLBI) [E] <(b) (6)> Fessel, Josh (NIH/NHLBI) [E]
<(b) (6)> Cc: Wholley, David (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)>
Melencio, Chery: (FNIH) [T] <(b) (6)> Desrosiers, Betsy <(b) (6)> Eric Hughes
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>
Tountas Karen (FNIH) [T] <(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Adam, Stacey (FNIH) [T]
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Prabhavathi Fernandes
<(b) (6)> Diamond, Michael <(b) (6)> Rose Li
<(b) (6)> Dana Carluccio <(b) (6)> Lagos, Enrique (NIH/NCATS) [E]
<(b) (6)> Jonson, Samantha (NIH/NCATS) [E] <(b) (6)> Gonzalez, Nina
<(b) (6)> Simon, Dina (NIH/OD) [C] <(b) (6)> Burrus-Shaw, Cyndi (NIH/OD) [E]
<(b) (6)> Rodriguez, Robin D <(b) (6)> Dave Frankowski
<(b) (6)> antoinette_baric <(b) (6)> Lowy, Douglas
(NIH/NCI) [E] <(b) (6)> Florence, Clint (NIH/NIAID) [E] <(b) (6)> Nancy Haigwood
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E]
<(b) (6)> Hawk, Harrison <(b) (6)> Mason, Stephen <(b) (6)>
(b) (6) Lumsden, Joanne (NIH/NCATS) [C]
<(b) (6)> K C Kent Lloyd <(b) (6)>
Subject: RE: ACTIV Preclinical full working group

Dear Preclinical Working Group,

Thank you all for attending our ACTIV preclinical full working group meeting yesterday. Please see attached for the notes from our discussion, and let us know if you all have any additions or amendments. We have also attached a slide with the subgroup updates we didn't get to during the meeting.

Also attached please find the finalized report for the SARS-CoV-2 summit on antiviral drug development. Sharing with the WG for awareness.

Best Regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP

GADB0000003935-2517531

Tel/Direct: (b) (6)
www.deloitte.com

-----Original Appointment-----

From: Menetski, Joseph (FNIH) [T] <(b) (6)>

Sent: Friday, October 2, 2020 2:19 PM

To: Menetski, Joseph (FNIH) [T]; Hild, Sheri (NIH/OD) [E];

(b) (6)

3;

(b) (6)

(b) (6)

(b) (6)

; Baric, Ralph;

(b) (6)

Ottinger, Elizabeth (NIH/NCATS) [E]; Colvis, Christine (NIH/NCATS) [E]; Hewitt, Judith

(NIH/NIAID) [E]; Deming, Damon (FDA/CDER);

(b) (6)

;

Parker, Ashley (NIH/OD) [E]; Collins, Francis (NIH/OD) [E];

(b) (6)

Adams, Peter

(OS/ASPR/BARDA); Rao, Srinivas; Qashu, Felicia (NIH/OD) [E]; Tomas Cihlar; Pitt, Margaret L CIV USARMY MEDCOM

USAMRIID (USA), Panturieri, Antonello (NIH/NHLBI) [E]; Charette, Marc (NIH/NHLBI) [E], Fessel, Josh (NIH/NHLBI) [E];

(b) (6)

Cc: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Melencio, Cheryl (FNIH) [T]; Desrosiers, Betsy; Eric

Hughes; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Tountas,

Karen (FNIH) [T]; Santos, Michael (FNIH) [T]; Adam, Stacey (FNIH) [T]; James, Stephanie (FNIH) [T]; Alvarez, Rosa Maria;

Kim, Elizabeth; Tolman, Brett; Wachtel, Jonathan; Prabhavathi Fernandes; Diamond, Michael; Rose Li; Dana Carluccio;

Lagos, Enrique (NIH/NCATS) [E]; Jonson, Samantha (NIH/NCATS) [E]; Gonzalez, Nina; Simon, Dina (NIH/OD) [C]; Burrus-

Shaw, Cyndi (NIH/OD) [E]; Rodriguez, Robin D; Dave Frankowski; antoinette_baric; Lowy, Douglas (NIH/NCI) [E];

Florence, Clint (NIH/NIAID) [E]; Nancy Haigwood; Stratton, Benjamin; Gadbois, Ellen (NIH/OD) [E]; Anderson, James

(NIH/OD) [E]; Hawk, Harrison; Mason, Stephen;

(b) (6)

Connelly, Sarah;

(b) (6)

Lumsden, Joanne (NIH/NCATS) [C]; K C Kent Lloyd;

(b) (6)

Subject: ACTIV Preclinical full working group

When: Wednesday, January 20, 2021 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom>.

(b) (6)

Changing time for preclinical WG

Joseph Menetski is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

<https://fnih.zoom.us/>

(b) (6)

Meeting ID: (b) (6)

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Dial by your location

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US (New York)

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US (San Jose)

US (Tacoma)

US (Houston)

Meeting ID: (b) (6)

Passcode: (b) (6)

Find your local number: <https://fnih.zoom>.

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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-ME_ENCIOC]
Sent: 8/18/2020 2:23:39 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael [(b) (6)]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Pao, William [(b) (6)]; Plump, Andrew [(b) (6)]; Stoffers, Paul [(b) (6)]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Coavis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [(b) (6)]; Anderson, Margaret [(b) (6)]; Chen, Helen [(b) (6)]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user0efa7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=users3ed7188]; Tolman, Brett [(b) (6)]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6)]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Conrad, Patricia
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 | (b) (6) Protasiewicz, Ann | (b) (6) Riccobene, Kim
 | (b) (6) Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togash, Mieko (NIH/NCI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Underwood, Nancy
 | (b) (6) Zottoli, Jessica | (b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Hughes, Karen (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugheskp]; Lagos, Enr que
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagoses]; Sepulveda, Dorina (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD)
 [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Tajalli, Ada (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]

Subject: ACTIV EC & Working Group Co-Chair Meeting

Location: <https://nih.zoom.us/> (b) (6)

Start: 9/9/2020 1:00:00 PM

End: 9/9/2020 2:00:00 PM

Show Time As: Busy

Required Attendees: Collins, Francis (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Fauci, Anthony (NIH/NIAID) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Marks, Peter (FDA/CBER); Pao, William; Plump, Andrew; Stoffels, Paul; Woodcock, Janet (FDA/CDER); Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurlla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; Hawk, Harrison; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]

Optional Attendees: Anderson, James (NIH/OD) [E]; Austin, Christopher (NIH/NCATS) [E]; Burklow, John (NIH/OD) [E]; Castillejos, Carlos; Culp, Michelle (NIH/OD) [E]; FNIH Central Account; Gadbois, El en (NIH/OD) [E]; Hallett, Adrienne (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Myles, Renate (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E];

Wolinetz, Carne (NIH/OD) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; McManus, Ayanna (NIH/OD) [E]; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Hughes, Karen (NIH/OD) [E]; Lagos, Ennque (NIH/NCATS) [E]; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Tajalli, Ada (NIH/OD) [E]

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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Passcode: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Woodcock, Janet [REDACTED] (b) (6)
Sent: 5/13/2020 1:37:51 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group
Flag: Follow up

Yes you can share. It's a bit out of date. As I said I'm doing a deeper dive on convalescent plasma and the neutralizing MoAbs. Should have soon. Need to fill in detail of all planned DOD and NIH studies. Should get to that this week. Jw

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6)
Date: May 12, 2020 at 8:48:22 PM EDT
To: Woodcock, Janet <[REDACTED]> (b) (6)
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi Janet,

I just got to this e-mail (it's been that kind of day). Wow, there is a LOT of useful information here. May I share with ACTIV leadership?

Francis

From: Woodcock, Janet <[REDACTED]> (b) (6)
Sent: Tuesday, May 12, 2020 5:01 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6)
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6)
Sent: Tuesday, May 12, 2020 1:31 PM
To: Woodcock, Janet <[REDACTED]> (b) (6) <[REDACTED]>
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

5 pm? (b) (6) if you can. Otherwise after 7 pm is good

From: Woodcock, Janet <[REDACTED]> (b) (6)
Sent: Tuesday, May 12, 2020 1:08 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6)
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

No have to brief higher ups. Later better. Jwv

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> (b) (6)
Date: May 12, 2020 at 12:49:32 PM EDT

COLL0000021851-2517533

To: Woodcock, Janet < (b) (6) >
Subject: RE: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Yes, I would like that. Can you do 3:30?

From: Woodcock, Janet < (b) (6) >
Sent: Tuesday, May 12, 2020 11:28 AM
To: Collins, Francis (NIH/OD) [F] < (b) (6) >
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Can we discuss before tomorrow? jw

From: Wholley, David (FNIH) [T] < (b) (6) >
Sent: Tuesday, May 12, 2020 10:46 AM
To: Collins, Francis S (NIH) < (b) (6) >; Stoffels, Paul [JJCUS] < (b) (6) >; Fauci, Anthony S (NIH) < (b) (6) >; Gibbons, Gary H (NIH) < (b) (6) >; Woodcock, Janet < (b) (6) >; Pao, William < (b) (6) >; Dolsten, Mikael < (b) (6) >

Cc: Colvis, Christine M (NIH) < (b) (6) >; Desrosiers, Betsy < (b) (6) >; Hughes, Eric < (b) (6) >; Read, Sarah W (NIH) < (b) (6) >; Jansen, Kathrin < (b) (6) >; Kurilla, Michael G (NIH) < (b) (6) >; Lowy, Douglas R (NIH) < (b) (6) >; Young, John < (b) (6) >; Freire, Maria C (NIH) < (b) (6) >; Tabak, Lawrence A (NIH) < (b) (6) >; Lane, Henry C (NIH) < (b) (6) >; Parker, Ashley S (NIH) < (b) (6) >; Anderson, James M (NIH) < (b) (6) >; Austin, Christopher P (NIH) < (b) (6) >; Wolinetz, Carrie D (NIH) < (b) (6) >
Subject: FW: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Dear ACTIV Executive Committee Members:

Please see the attached letter from the ACTIV Therapeutics-Clinical Working Group received this morning, for consideration on tomorrow morning's Executive Committee teleconference. While we expect the proposals contained herein will be one major topic of discussion, the purpose of the meeting is to hear from all of the Working Group co-chairs (copied on this note) regarding what is working and where they may be facing challenges in ACTIV, and jointly discuss strategy moving forward.

David

From: Adam, Stacey (FNIH) [T] < (b) (6) >
Sent: Tuesday, May 12, 2020 9:52 AM
To: Wholley, David (FNIH) [T] < (b) (6) >
Cc: Read, Sarah (NIH/NIAD) [E] < (b) (6) >; Eric Hughes < (b) (6) >; Carlos O Garner < (b) (6) >; Judy Currier < (b) (6) >; Keith Gottesdiener < (b) (6) >; Amanda Peppercorn < (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) >; Higgs, Elizabeth (NIH/NIAD) [E] < (b) (6) >
Subject: Letter to the ACTIV Executive Committee from the Therapeutics-Clinical Working Group

Hi David,

Please find attached a letter from the Therapeutics-Clinical Working Group to the ACTIV Executive Committee for their consideration. Overall, the letter is meant to relate some broad challenges and issues that the Therapeutics-Clinical group thinks the ACTIV PPP is facing, as well as some very specific requests for assistance from the ACTIV EC for our team.

Please relay this to the ACTIV EC for their review. Our group would welcome any feedback they have.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Melsheimer, Rich [CNTNL] [(b) (6)]
Sent: 10/16/2020 9:12:01 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]
CC: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bfdccfda71ced-jatkinso]; Chang, Soju (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99b3263e72a94bfa9ded3f82c4dae59c-changsoju]; (b) (6) Gavin, Brian [(b) (6)]; Sadeh, Jonathan [(b) (6)]; Beumont-Mauviel, Maria [JRDUS] [(b) (6)]; Bharucha, David [(b) (6)]; Ferguson, William [(b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; LaVange, Lisa M [(b) (6)]; Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Gardner, Bobbi (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dd21d20185e4e46a20a6eb89c314580-gardnerbw]; Sandeep Menon [(b) (6)]; Yong, Florence H [(b) (6)]; Trank, Christina [(b) (6)]; Moyo, Vusi [(b) (6)]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Kimmel, Bridget [JRDUS] [(b) (6)]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Marti, Emily (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=970fb6ea63944699aa433fb034a0f63f-carlsone]; Eisnor, Derek (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae393740634d4ec9954494c0c2ef669a-Derek.Eisno]; (b) (6) Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; Montgomery, Stephanie [(b) (6)]; O'Sullivan, Alexandra [(b) (6)]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Neta Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d10b8fd5dff411eb1d6f8f4892e27e3-nnelson.tec]; Butler, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4782eaa72024479197826e3d71d5584c-sbutler.tec]; Danie, Benjamin Jr, M.D., Ph.D. [(b) (6)]; Theresa Jasion [(b) (6)]; Molina, Daniel [(b) (6)]; Rose Beci [(b) (6)]; Lind, Brian (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=486ebcc6ebe34d08a691e66632ed5005-lindbj]; O'rourke, Anna (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a43de8d7c474c538615405753ccfb6c-Anna.O_rour]; Lori Hudson, Ph.D. [(b) (6)]; Huyen Cao < (b) (6) > [(b) (6)]; Huyen Cao [(b) (6)]; Brody, Betty (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecad8c87c49d4f018bd2530beaf4a30d-Betty.Brody]; Chiang, Anna (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa42127fa32b4d0fa0ccce5799cf419f-Anna.Chiang]; Schmidt, Jeffrey (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3431da5ab88f4204858d4c6fe19aaa7a-Jeffrey.Sch]
Subject: Re: 1st ACTIV-1 patient has been randomized

1999 to go!!

It's been a big day for ACTIV-1!!

Thanks to everyone!

Rich

Sent from my iPhone

On 16 Oct 2020, at 22:49, Austin, Christopher (NIH/NCATS) [E] <(b) (6)> wrote:

Woohoo that was fast! Thank you Bill and Jane and team!

All best,

Chris

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>

Sent: Friday, October 16, 2020 4:48 PM

To: Boucher, Cynthia (NIH/NCATS) [E] <(b) (6)> Atkinson, Jane (NIH/NCATS) [E]

<(b) (6)> Chang, Soju (NIH/NCATS) [E] <(b) (6)> ' (b) (6)

<(b) (6)> 'Gavin, Brian' <(b) (6)> 'Sadeh, Jonathan'

<(b) (6)> 'Melsheimer, Rich [CNTNL]' <(b) (6)> 'Beumont-Mauviel,

Maria [JRDUS]' <(b) (6)> 'Bharucha_David' <(b) (6)

'Ferguson_William' <(b) (6)> Eric Hughes <(b) (6)> Read,

Sarah (NIH/NIAID) [E] <(b) (6)> 'LaVange, Lisa M' <(b) (6)> Proschan,

Michael (NIH/NIAID) [E] <(b) (6)> Gardner, Bobbi (NIH/NCATS) [E]

<(b) (6)> 'Sandeep Menon' <(b) (6)> 'Yong, Florence H

<(b) (6)> 'Trank, Christina' <(b) (6)> 'Moyo, Vusi'

<(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> 'Kimmel, Bridget [JRDUS'

<(b) (6)> Adam, Stacey (FNIH) [T] <(b) (6)> Marti, Emily (NIH/NCATS) [E]

<(b) (6)> Eisnor, Derek (OS/ASPR/BARDA) <(b) (6)

' <(b) (6)> <(b) (6)> Austin, Christopher (NIH/NCATS) [E]

<(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Woodcock, Janet

(FDA/CDER) <(b) (6)> Mason, Robin (OS/ASPR/BARDA)

<(b) (6)

Cc: 'Montgomery, Stephanie' <(b) (6)> O'Sullivan_Alexandra

<(b) (6)> Stock, Thomas (HHS/IOS) <(b) (6)> Neta Nelson

<(b) (6)> Butler, Sandy <(b) (6)> Daniel Benjamin Jr, M.D., Ph.D.

<(b) (6)> Theresa Jasion <(b) (6)> Molina, Daniel

<(b) (6)> Rose Beci <(b) (6)> Lind, Brian (NIH/NCATS) [E]

<(b) (6)> Mason, Robin (OS/ASPR/BARDA) <(b) (6)> O'rourke, Anna

(OS/ASPR/BARDA) (CTR) <Anna. (b) (6)> Austin, Christopher (NIH/NCATS) [E]

<(b) (6)> Lori Hudson, Ph.D. <(b) (6)> "Huyen Cao"

<(b) (6)> <"Huyen Cao" <(b) (6)> Huyen Cao

<(b) (6)> Brody, Betty (OS/ASPR/BARDA) <(b) (6)> Chiang, Anna

(OS/ASPR/BARDA) <(b) (6)> Schmidt, Jeffrey (OS/ASPR/BARDA)

<(b) (6)

Subject: 1st ACTIV-1 patient has been randomized

Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all!

Sam B

Sam Bozzette, MD, PhD

Chief Medical Officer

Immediate Office of the Director

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/16/2020 4:11:37 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tountas Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: FW: ACTIV Home Nursing Playbook ready for use!

Since you asked...

From: Tountas, Karen (FNIH) [T] <(b) (6)>
Sent: Thursday, July 16, 2020 11:05 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: RE: ACTIV Home Nursing Playbook ready for use!

Just an FYI... I sent this final version to the ACTIV-2 ops team and received this from Judy Carrier "Thanks Karen, This is really helpful and just in time as we work to finalize our plans for home health in ACTIV-2. It will be of great value to the ACTIV-2 team."

Good to know all that work was not in vain! Let's hope the next four are also helpful for ACTIV 😊

From: Tountas, Karen (FNIH) [T]
Sent: Thursday, July 16, 2020 8:58 AM
To: Colvis, Christine (NIH/NCATS) [E] <(b) (6)>; Hughes, Eric <(b) (6)>; Jansen, Kathrin <(b) (6)>; Lowy, Douglas (NCI) <(b) (6)>; Read, Sarah (NIH/NIAID) [E] <(b) (6)>; Young, John <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)>; James, Stephanie (FNIH) [T] <(b) (6)>; Menetski, Joseph (FNIH) [T] <(b) (6)>; Santos, Michael (FNIH) [T] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Desrosiers, Betsy <(b) (6)>; Kurilla, Michael (NIH/NCATS) [E] <(b) (6)>; Kelly, Eileen <(b) (6)>; Wachtel, Jonathan <(b) (6)>
Subject: ACTIV Home Nursing Playbook ready for use!

Dear ACTIV Working Group co-chairs,

On behalf of the ACTIV Clinical Trial Capacity Working Group, I am pleased to announce the completion of the ACTIV Home Nursing Playbook (attached). Many thanks to Betsy Desrosiers and Eileen Kelly (cc'd) and their teams at Merck and Novartis, respectively, for sharing their knowledge, lessons learned, and materials to enhance and accelerate ACTIV's clinical trial efforts. And, many thanks to Jonathan and Olivia (Deloitte) for creating an organized and user-friendly structure for these playbooks.

We know that the ACTIV-2 operations team, who has used an earlier draft of this playbook, found the details enclosed very useful and we hope that other COVID-focused clinical trial protocol and operations teams will also. Please feel free to distribute to your teams, and provide any and all feedback (positive and constructive critiques).

Of note, Betsy and Eileen have offered to make themselves and their team members available to walk through the playbook with clinical trials teams as requested.

With best regards,
Karen

Karen H. Tountas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/31/2020 12:53:31 AM
To: Dolsten, Mikael [(b) (6)]
CC: Sogaard, Morten [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Cheng, Seng [(b) (6)]; Protasiewicz, Ann [(b) (6)]
Subject: RE: [EXTERNAL] RE: Preparation for Monday's AMP Gene Therapy teleconference

Sounds like a good idea. Let me know if you think we all need to talk more on Monday.

From: [(b) (6)]
Sent: Saturday, May 30, 2020 6:45 PM
To: Wholley, David (FNIH) [T] < [(b) (6)]>
Cc: Sogaard, Morten < [(b) (6)]>; Menetski, Joseph (FNIH) [T] < [(b) (6)]>; Hoffmann, Steve (FNIH) [T] < [(b) (6)]>; Collins, Francis (NIH/OD) [E] < [(b) (6)]>; Marks, Peter (FDA/CBER) < [(b) (6)]>; Cheng, Seng < [(b) (6)]>; Protasiewicz, Ann < [(b) (6)]>
Subject: Re: [EXTERNAL] RE: Preparation for Monday's AMP Gene Therapy teleconference

Let's circulate the GTx proposal before HEVER as I think it was at a HEVER meeting a while ago that I and Francis brought to the table a proposal around GTx rare disease
Peter Marks has also been a driving force

We may at the end of HEVER ask for comments on the white paper GTx and encourage more groups to join.

Sent from my iPhone

On May 30, 2020, at 17:35, Wholley, David (FNIH) [T] < [(b) (6)]> wrote:

Hi, Morten,

Sorry for not responding sooner to your meeting notice but have been heads down on COVID (ACTIV) stuff. The final white paper is attached. I must confess I am not entirely sure what the agenda should be the call you arranged for Monday's, but am happy to jump on the phone if there needs to be a follow-up discussion. My official next step is to get the minutes from our EC call Friday (which our writer tells us I should have by Monday morning) and send out a formal ballot to the EC (we were missing Paul Stoffels and John Reed on Friday's call, unfortunately, and did not complete a final vote). If, as I expect, the formal vote is to proceed the typical next step is for FNIH to shop the white paper to companies that may be interested in joining the existing group to turn the white paper level plan into a final research plan with well-defined budgets and specific milestones FNIH would run that additional planning process (which Joe and Steve would lead). Normally I would think we'd use Hever as a venue to make the additional companies aware of the opportunity (and I imagine we do owe them a report out on the progress of this effort given that it originated there), but I understand the plan for this Tuesday's Hever

call is pretty much focused on the global response to COVID. I defer naturally to Mikael on how he'd like to handle this. Perhaps we can talk about that more on Monday.

Regards,

David

From: Sogaard, Morten <(b) (6)>
Sent: Saturday, May 30, 2020 12:12 PM
To: Menetski, Joseph (FNIH) [T] <(b) (6)> Hoffmann, Steve (FNIH) [T]
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> (b) (6) (b) (6) Marks, Peter (FDA/CBER)
<Peter.M (b) (6)>
Cc: Sogaard, Morten <(b) (6)> Cheng, Seng <(b) (6)>
Protasiewicz, Ann <(b) (6)>
Subject: Preparation for Monday's AMP Gene Therapy teleconference

Dear Joe, Steve and David,

Congratulations on the AMP Gene therapy white paper – that is an important milestone and achievement. I wondered if you could share the latest version that was shared at Friday's AMP meeting so we can share with the full group? Please, also let me/us know of any other pre-read material.

Dear Mikael, Francis and Peter,

I assume that the main focus of Monday's meeting will be to follow up on the AMP discussion and come together around next steps in a bit more detail?

Best wishes,
Morten

<AMP Gene Therapy Concept_5.29.2020.pdf>

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-ME.LENCIOC]

Sent: 1/12/2021 9:56:20 PM

To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [(b) (6) Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [(b) (6) Victoria Davey [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbeling, Emily (NIH/NIAID) [E] [(b) (6) Erck, Stan [(b) (6) Gadbois, Ellen (NIH/OD) [E] [(b) (6) Gibbons, Gary (NIH/NHLBI) [E] [(b) (6) Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) : Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [(b) (6)]; Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Messonnier, Nancy (CDC/DDID/NCIRD/OD) [(b) (6) Pandya, Hitesh [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramoni [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Tal ey Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Wholley, David (FNIH) [T] [(b) (6) Young, John [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6)]; Desrosiers, Betsy [(b) (6) Eric Hughes [(b) (6)]; Jansen, Kathrin [(b) (6)]; Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Anderson, James (NIH/OD) [E] [(b) (6) Burklow, John (NIH/OD) [E] [(b) (6) Carluccio, Dana [(b) (6) Castillejos, Carlos [(b) (6) FNIH Central Account [(b) (6) Hallett, Adrienne (NIH/OD) [E] [(b) (6)]; Lumsden, Joanne (NIH/NCATS) [C] [(b) (6) Myles, Renate (NIH/OD) [E] [(b) (6)]; Wolinetz, Carrie (NIH/OD) [E] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Margaret Anderson [(b) (6) Appell, Evan [(b) (6) Chen, Helen [(b) (6) Connelly, Sarah [(b) (6) Gonzalez, Nina [(b) (6) Hawk, Harrison [(b) (6) Mendelson, Jesse [(b) (6) Nasr, Hana [(b) (6) Sorosa, Alex [(b) (6)]; Stratton, Benjamin [(b) (6) btolman [(b) (6) Wachtel, Jonathan [(b) (6) Meltzer, Abbey (FNIH) [T] [(b) (6) Embry, Alan (NIH/NIAID) [E] [(b) (6) Venkayya, Rajeev [(b) (6) Rutter, Joni (NIH/NCATS) [E] [(b) (6) Cwalina, Alex [(b) (6) Kessler, David (HHS/IOS) [(b) (6) Bancel, Stephane [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Pangalos, Mene [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Reed, John [(b) (6) Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]

CC: Austin, Sarah (NIH/NIAID) [E] [aust (b) (6) Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Bell, Julie [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6)]; Carver, Trea (NIH) [C] [(b) (6)]; Caulfied, Anita [(b) (6)]; Coan, Amanda [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6)]; Dimishkov, Roxanne (NIH/NHLBI) [C] [(b) (6) Edl, Susan [(b) (6) Fuhrer, Nicole [(b) (6) Giorgi, Sara [(b) (6) Hoban, Michelle [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemaj, Varde [(b) (6) Jenkins, Christine S. [(b) (6) Lever, Susan [(b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [(b) (6) Martin, Melisa [(b) (6) McManus, Ayanna (NIH/OD) [E] [(b) (6) Minnich, Beth [(b) (6) Perala, Mie [(b) (6) Protasiewicz, Ann [(b) (6) Riccobene, Kim [(b) (6)]; Riffin, Mary [(b) (6)]

(b) (6)	Ripley, Nadege [(b) (6)	Schuster, Donna
(b) (6)	Sepulveda, Dorina (FNIH) [T]	(b) (6)	Simon, Dina (NIH/OD) [C]
(b) (6)	Suhana, Tina (NIH/VRC) [E]	(b) (6)	Thomas, Ashley (FDA/CDER)
(b) (6)	Wood, Gretchen (NIH/OD) [E]	(b) (6)	Togashi, Mieko (NIH/NCI) [E]
(b) (6)	Underwood, Nancy [(b) (6)	Zottoli, Jessica
(b) (6)	Hughes, Karen (NIH/OD) [E]	(b) (6)	Regan, Donna M
(b) (6)	Plenge, Robert [(b) (6)	Vessey, Rupert [
Burke, Leslie [(b) (6)	Moghminia, Mahtab (NIH/NCATS) [E]	(b) (6)
Lowy, Douglas (NIH/NCI) [E]	(b) (6)		

Subject: ACTIV Leadership Team Call #15

Location: <https://fnih.zoom.us/> (b) (6)

Start: 4/28/2021 12:30:00 PM

End: 4/28/2021 2:00:00 PM

Show Time As: Busy

Required Attendees: Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erpelding, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CBER); Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/OC); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos, FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachtel, Jonathan; Meltzer, Abbey (FNIH) [T]; Embry, Alan (NIH/NIAID) [E]; Venkayya, Rajeev; Rutter, Joni (NIH/NCATS) [E]; Cwalina, Alex; Kessler, David (HHS/IOS)

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [E]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melissa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Peralta, Mie; Protasiewicz, Ann; Riccobene, Kim; Riggan, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Dorina (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina (NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica; Hughes, Karen (NIH/OD) [E]; Regan, Donna M; Plenge, Robert; Vessey, Rupert; Burke, Leslie; Moghminia, Mahtab (NIH/NCATS) [E]; Lowy, Douglas (NIH/NCI) [E]

Joseph Menetski is inviting you to a scheduled zoom meeting.

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From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 5/29/2020 10:49:02 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30



On May 29, 2020, at 6:44 PM, Collins, Francis (NIH/OD) [E] < (b) (6) > wrote:

Yes, she is waiting to see the draft ppts and will advise on the strategy then.

Sent from my iPhone

On May 29, 2020, at 6:06 PM, Freire, Maria (FNIH) [T] < (b) (6) > wrote:

Francis - have you had a chance to chat with Janet to coordinate messages? She is critical - in her low-key way, she is able to carry a huge part of the load. Moncef knows she has a rock-solid reputation with industry folks. And, of course, she was the one who asked for the money. M.

On May 29, 2020, at 5:59 PM, Collins, Francis (NIH/OD) [E] < (b) (6) > wrote

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note - has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] < (b) (6) >
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >
Cc: Adam, Stacey (FNIH) [T] < (b) (6) > Freire, Maria (FNIH) [T] < (b) (6) > Gonzalez, Nina < (b) (6) > Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here is the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1; it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hVIG (sponsored by NIAID) – in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV 2* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS "Master" Network) – (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
 - * current priority

[for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base

- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
[Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
 - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
 - Protocol is 80% complete

- Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
- All three companies have written their sections of the protocols, which are being merged into the master design
 - Working with OWS/BARDA on choice of CRO to run the trial; r (b) (5)
- “ACTIV-4” Protocol for anticoagulants
 - Need bullets from NHLBI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the cl nical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
 (b) (6)

fnih.org
 11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

<Responses to Qs re AC Clinical Trial Strategy 052920 final fsc.docx>

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/1/2020 4:48:17 AM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) [(b) (6) (b) (6) (b) (6) Cavaleri Marco (b) (6) (b) (6) (b) (6) Greg Glenn (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; (b) (6) (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) | (b) (6) Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56f8be4598a57b423d484dcf9f-offit email]; (b) (6) Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) Tal Zaks | (b) (6) (b) (6) (b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]; MDouogui@its.jnj.com; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; pgilbert@scharp.org; (b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda]; (b) (6) Hamilton, Holli (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00bSeaa4222d0576cc-Holli.Hamli]; (b) (6) (b) (6) Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; MLeysen@its.jnj.com; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; (b) (6) (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbd9cc56f8be4598a57b423d484dcf9f-offit.email]; (b) (6) (b) (6) Laurent Humeau | (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Hotez, Peter Jay | (b) (6) (b) (6) (b) (6) Tal Zaks | (b) (6) (b) (6) Greg Glenn | (b) (6) (b) (6)

CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay] (b) (6)
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(NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b) (6) Jeneffer Haynes (b) (6)]; (b) (6)
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Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj];
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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] (b) (6)]; Hughes, Eric] (b) (6) Kurilla, Michael (NIH/NCATS) [E]
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(CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
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] (b) (6)]; Brian Rosen] (b) (6)]; Cheryl Keech] (b) (6)];
(b) (6) (b) (6) Bethany Stokes
] (b) (6)]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; 'Wachtel, Jonathan' (b) (6) Stratton,
Benjamin] (b) (6) Anderson, Margaret] (b) (6)

Subject: Notes from the ACTIV Vaccines Working Group meeting

Attachments: 2020-05-28 Vaccines Working Group meeting Summary Notes.docx; ACTIV_Presentation_MBiggerstaff.pdf

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

Thank you for your participation in the last meeting of the Vaccines Working Group. Attached are the notes from that meeting and the slides that Matt Biggerstaff presented.

Please let us know if you have any questions or suggestions. We look forward to engaging with you in this week's meetings.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, May 27, 2020 1:12 PM
Subject: Agenda for ACTIV Vaccines Working Group meeting: Tomorrow, 28 May

Dear Vaccines Working Group and Vaccines Clinical Trials Sub-Group members,

The agenda for **Vaccines Working Group meeting** tomorrow (Thursday) at 2pm ET (11am PT / 8pm CEST) is:

- Matt Biggerstaff, from CDC's modeling team, will present on predictive modeling of incidence to inform vaccine efficacy trials
- Time permitting, we will discuss updates from the Sub-Groups

Given the importance of the first agenda item to the Vaccines Clinical Trials Sub-Group, we are inviting that group to join the meeting. The calendar invite follows this note. As a reminder, we have two meetings scheduled tomorrow, and many of you will also receive an email about the Vaccines Clinical Trials Sub-Group meeting (at 11am ET).

We also want to provide a preview of a coming set of requests: As we have previously discussed, NIAID is constituting a DSMB for the efficacy trials that are implemented with US government funding. The Vaccines Clinical Trials Sub-Group was asked for DSMB member recommendations: thanks to those who sent input. We will be sharing a list of potential DSMB members from NIAID with the Vaccines Clinical Trials Sub-Group (cc'ing the Working Group) today for feedback. Based on that feedback, NIAID will propose a list of members and alternates. We will circulate that list to the Vaccines Working Group (cc'ing the Sub-Group) for final input before NIAID finalizes the list and reaches out to proposed members. We apologize in advance for the short turn-around times that will be requested given the necessity of finalizing the DSMB members in time for an early July trial start.

We're looking forward to the meeting tomorrow. Please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
(b) (6) fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Stay at the forefront of FNIH news: [fnih.org newsletter](https://fnih.org/newsletter)

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 4/17/2020 8:04:45 PM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes |
| (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn | (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Bascles, Lionel | (b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Michael | (b) (6) Desrosiers, Betsy | (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Rose Li Central Account | (b) (6) Lucas Smalldon | (b) (6) Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Kelly Beazley | (b) (6) Wung, Peter /US | (b) (6) Greg Richards | (b) (6)
Subject: RE: ACTIV TX-Clinical WG Master Protocol Subgroup - 2nd Meeting (Materials Attached)

Hi Sam,

I believe we will be trying to take into account smaller Phase II trials, as well. More on that next week, we have been reviewing some additional protocols. Appreciate you raising it for clarification.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: (b) (6) Mobile: (b) (6)

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>

Sent: Thursday, April 16, 2020 5:34 PM

To: Adam, Stacey (FNIH) [T] <(b) (6)> Butterson, Joan <(b) (6)> Collins, Sylva
(FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER)
<(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener
<(b) (6)> Eric Hughes <(b) (6)> LaVange, Lisa M <(b) (6)>
Elliott Levy <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah
(NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn <(b) (6)> Price, Dionne
(FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li
(FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Bascles, Lionel
<(b) (6)> Dickens, Jim (NIH/NCATS) [C] <(b) (6)> Stein, Peter (FDA/CDER)
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Cc: Mary Biggs <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)>
Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Elizabeth Kim
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<(b) (6)> Kelly Beazley <(b) (6)> Wung, Peter /US
<Peter. (b) (6)> Greg Richards <(b) (6)>

Subject: RE: ACTIV TX-Clinical WG Master Protocol Subgroup - 2nd Meeting (Materials Attached)

Hello:

Wondering where in development that agents would be candidates for inclusion into the platform trial(s) need to be? The tone of the discussion seems to be indicate that we are intending these protocols to support relatively large phase 3 evaluations. What about products that need phase 2 (particularly from small companies)? Would we try to roll them in (seems hard), generate another set of master protocols, leave them to flourish (or not) on their own, or something else?

S

-----Original Appointment-----

From: Adam, Stacey (FNIH) [T] <(b) (6)>

Sent: Wednesday, April 15, 2020 6:10 PM

To: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; LaVange, Lisa M; Elliott Levy, Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Bascles, Lionel; Dickens, Jim (NIH/NCATS) [C]; Stein, Peter (FDA/CDER); Vincent, Michael; Desrosiers, Betsy; Goff, David (NIH/NHLBI) [E]

Cc: Mary Biggs; Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Rose Li Central Account; Lucas Smalldon; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Kelly Beazley; Wung, Peter /US; Greg Richards

APAR0000023353-2517540

Subject: ACTIV TX-Clinical WG Master Protocol Subgroup - 2nd Meeting (Materials Attached)
When: Thursday, April 16, 2020 11:00 AM-12:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://zoom.us/> (b) (6)

Dear ACTIV Therapeutics-Clinical WG Master Protocol Subgroup Members,

Thank you all for being so quick to reply and making yourselves available for a second meeting on such short notice!

As discussed yesterday, we have tried to synthesize the main points from our discuss and put together just a few slides to pressure test what we thought we heard.

As we think we defined the patient populations and the order of priority with which we should address them during our last meeting. We hope to come out of today's meeting with a decision on whether to engage/sign on to existing master protocols and enhance them (new agents, more resources, more sites, etc.) or to create a who new protocol.

Please see attached:

1. Agenda
2. Slides for today's meeting
3. Copies of the protocols for today's discuss that we could access
 - a. ACTG
 - b. ACTT v2
 - c. REMAP-CAP + Pandemic Amendment
 - i. <https://www.remapcap.org/coronavirus> provides a summary of changes to the REMAP-CAP protocol in order to update to the COVID population

NOTE: We are still working on access to ORCHID.

Kind regards,
Stacey, on behalf of the ACTIV TX-Clinical WG

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/26/2020 11:43:09 AM
To: Allen-Gifford, Patrice (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67262490d6d441b48efec1aff0700250-al engrffor]
Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Ok, thank you.

From: Allen-Gifford, Patrice (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, August 26, 2020 7:34 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Yes, thanks, I was on but I'm not sure all of them were. Also, I am including the entire zoom link info (include call in #s although I think just the zoom info should be sufficient.

From: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, August 26, 2020 7:32 AM
To: Allen-Gifford, Patrice (NIH/OD) [E] < (b) (6) >
Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

That's a great idea -- it was the COVID-19 ICD Update conference call.

Thanks,
Ashley

From: Allen-Gifford, Patrice (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, August 26, 2020 7:28 AM
To: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thanks Ashley. I have it ready to go and had made the same adjustments. One question: rather than conference call, should it reference the COVID-19 call so ICDs who didn't participate in that won't think they missed an ICD meeting?

From: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Sent: Wednesday, August 26, 2020 7:25 AM
To: Collins, Francis (NIH/OD) [E] < (b) (6) >, Allen-Gifford, Patrice (NIH/OD) [E] < (b) (6) >
Cc: Wholley, David (FNIH) [T] < (b) (6) >, Melencio, Cheryl (FNIH) [T] < (b) (6) >, Gladman, Jordan (NIH/OD) [E] < (b) (6) >
Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Thank you, Francis.

Good morning Patrice,

I've made a few adjustments to the email below to go out to the ICD ONLY list this morning and reattached the materials.

Thanks,
Ashley

To: ICD-ONLY-L@LIST.NIH.GOV

Cc: Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] (b) (6)

Bcc: Parker, Ashley (NIH/OD) [E] (b) (6)

Dear Colleagues,

As discussed during our conference call yesterday, ICDs (**principals only please; no surrogates or additional staff**) are invited to join the virtual ACTIV leadership team meeting **today August 26, 3:00-4:00pm**. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in "listen-only" mode during the meeting.

Thank you,
Francis

From: Collins, Francis (NIH/OD) [E] <(b) (6)>

Sent: Wednesday, August 26, 2020 5:57 AM

To: Parker, Ashley (NIH/OD) [E] <(b) (6)>

Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) ; Gladman, Jordan (NIH/OD) [E] (b) (6) ; Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)>

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Be sure to change the text of the e-mail from "tomorrow" to "today".

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, August 26, 2020 5:56 AM

To: Parker, Ashley (NIH/OD) [E] <(b) (6)>

Cc: Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T] (b) (6) ; Gladman, Jordan (NIH/OD) [E] (b) (6) Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)>

Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Yes, this note would be great. Looping in Exec Sec to ask that it be sent first thing this morning.

Francis

From: Parker, Ashley (NIH/OD) [E] <(b) (6)>

Sent: Tuesday, August 25, 2020 10:52 PM

To: Collins, Francis (NIH/OD) [E] (b) (6)

Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) ; Gladman, Jordan (NIH/OD) [E] (b) (6)

Subject: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

Hi Francis,

To ensure the ICDs receive the information for the ACTIV LT meeting tomorrow – would you like to forward the following to the ICD only list. Below is a draft note for consideration.

To: ICD-ONLY-L@LIST.NIH.GOV

APAR0000010277-2517541

Cc: Wholley, David (FNIH) [T] < (b) (6) Melencio, Cheryl (FNIH) [T] < (b) (6)

Dear Colleagues,

As discussed during our conference call this afternoon, ICDs (principals only please; no surrogates or additional staff) are invited to join the virtual ACTIV leadership team meeting tomorrow August 26, 3:00-4:00pm. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in "listen-only" mode during the meeting.

Thank you,
Francis

From: Melencio, Cheryl (FNIH) [T] < (b) (6) **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, August 25, 2020 9:47 PM
To: Austin, Christopher (NIH/NCATS) [E] < (b) (6) Bancel, Stephane
< (b) (6) Carter, Kara < (b) (6) Cavaleri, Marco
< (b) (6) Cihlar, Tomas (b) (6) Collins, Francis (NIH/OD) [E]
< (b) (6) ; Corey, Larry < (b) (6) Culp, Michelle (NIH/OD) [E] < (b) (6)
Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Dolsten, Mikael (b) (6) >; Erbeling,
Emily (NIH/NIAID) [E] < (b) (6) Erck, Stan < (b) (6) Fauci, Anthony (NIH/NIAID) [E]
(b) (6) Freire, Maria (FNIH) [T] < (b) (6) ; Gadbois, Ellen (NIH/OD) [E]
; Gibbons, Gary (NIH/NHLBI) [E] (b) (6) >; Hudson, Thomas
(b) (6) >; James, Stephanie (FNIH) [T] < (b) (6) Johnson, Robert (OS/ASPR/BARDA)
(b) (6) ; Kramer, Lynn (b) (6) Lane, Cliff (NIH/NIAID) [E] (b) (6)
Lepore, John (b) (6) >; Marks, Peter (FDA/CBER) < (b) (6) ; Marston, Hilary
(NIH/NIAID) [E] (b) (6) >; Mascola, John (NIH/VRC) [E] < (b) (6) Meeker, David
< (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Messonnier, Nancy
(CDC/DDID/NCIRD/OD) (b) (6) ; Pandya, Hitesh < (b) (6) >; Pangalos, Mene
< (b) (6) . Pao, William <will (b) (6) Parker, Ashley (NIH/OD) [E]
< (b) (6) Paul, Steve < (b) (6) Perlmutter, Roger < (b) (6)
Plenge, Robert (b) (6) ; Plump, Andy (b) (6) ; Rachel Ramoni
< (b) (6) Rasi, Guido < (b) (6) Reed, John < (b) (6) Reese, David
(b) (6) >; Rouse, Doris < (b) (6) Santos, Michael (FNIH) [T] < (b) (6) ; Skovronsky,
Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) ; Stoffels, Paul
< (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) ; Talley, Michael
< (b) (6) Tsai, John < (b) (6) Vessey, Rupert (b) (6) ; Virgin, Skip
< (b) (6) ; Wholley, David (FNIH) [T] < (b) (6) Woodcock, Janet (FDA/CDER)
(b) (6) ; Young, John < (b) (6) Colvis, Christine (NIH/NCATS) [E]
(Desrosiers, Betsy (b) (6) : Eric Hughes
< (b) (6) ; Jansen, Kathrin (b) (6) Kurilla, Michael (NIH/NCATS) [E]
(Lowy, Douglas (NCI) (b) (6) >; Read, Sarah (NIH/NIAID) [E] (b) (6) ;
Young, John (b) (6)
Cc: Adam, Stacey (FNIH) [T] < (b) (6) Alvarez, Rosa < (b) (6) Anderson, Margaret
(b) (6) ; Chen, Helen < (b) (6) Elsaid, Olivia (b) (6) ;
Gonzalez, Nina (b) (6) >; Hawk, Harrison (b) (6) ; Menetski, Joseph (FNIH) [T]
(b) (6) ; Santos, Michael (FNIH) [T] < (b) (6) Stratton, Benjamin < (b) (6)
btolman < (b) (6) Tountas, Karen (FNIH) [T] < (b) (6) Wachtel, Jonathan
(b) (6) Wholley, David (FNIH) [T] (b) (6) ; Anderson, James (NIH/OD) [E]
(b) (6) Austin, Christopher (NIH/NCATS) [E] < (b) (6) Burklow, John (NIH/OD) [E]
< (b) (6) Castillejos, Carlos < (b) (6) Culp, Michelle (NIH/OD) [E]
<michelle.culp@nih.gov>; FNIH Central Account (b) (6) >; Freire, Maria (FNIH) [T]
< (b) (6) Gadbois, Ellen (NIH/OD) [E] < (b) (6) >; Hallett, Adrienne (NIH/OD) [E]

(b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Myles, Renate (NIH/OD) [E]
 (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) . Tabak, Lawrence (NIH/OD) [E]
 (b) (6) ; Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Burklow, John (NIH/OD) [E]
 < (b) (6) ; Gorman, Greta (FNIH) [T] (b) (6) >; Hallett, Adrienne (NIH/OD) [E]
 (b) (6) ; Meltzer, Abbey (FNIH) [T] (b) (6) >; Myles, Renate (NIH/OD) [E]
 < (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Lucas Smalldon
 (b) (6) Villafana, Tonya < (b) (6) >; Brian Rosen
 (b) (6)

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E2283685FF4E9988E3770CFC7EE770-TABAKL]
Sent: 4/30/2020 4:54:14 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: Re: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Certainly agree.

From: "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Date: Thursday, April 30, 2020 at 12:50 PM
To: "Wholley, David (FNIH) [T]" <(b) (6)> Francis Collins <(b) (6)>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <(b) (6)> "Freire, Maria (FNIH) [T]" <(b) (6)>
Subject: Gilead and ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

I received an email yesterday (prior to the press release) from a relatively senior scientist that Gilead has re-considered and would like to be part of ACTIV. I was going to mention it on the call this afternoon. I think having them as part of ACTIV – given they have a strong track-record and likely the first directly acting anti-viral - would be good.

Cliff

From: "Wholley, David (FNIH) [T]" <(b) (6)>
Date: Thursday, April 30, 2020 at 10:18 AM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)>
Subject: FW: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

FYI, something to think about.

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>
Sent: Thursday, April 30, 2020 9:19 AM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Butterson, Joan <(b) (6)> Collins, Sylvia
(FDA/CDER) <(b) (6)> Judy Currier <(b) (6)> De Claro, R. Angelo (FDA/CDER)
<(b) (6)> Mark Eisner <(b) (6)> Keith Gottesdiener
<(b) (6)> Eric Hughes <(b) (6)> LaVange, Lisa M <(b) (6)>
Elliott Levy <(b) (6)> Sandeep Menon <(b) (6)> Amanda Peppercorn
<(b) (6)> Proschan, Michael (NIH/NIAID) [E] <(b) (6)> Read, Sarah
(NIH/NIAID) [E] <(b) (6)> Amanda Peppercorn <(b) (6)> Price, Dionne
(FDA/CDER) <(b) (6)> Rubin, Daniel B. (FDA/CDER) <(b) (6)> Shen, Yuan Li
(FDA/CDER) <(b) (6)> Farley, John (FDA/CDER) <(b) (6)> Goff, David (NIH/NHLBI)
[E] <(b) (6)> Vincent, Michael <(b) (6)>
Cc: Mary Biggs <(b) (6)> Demarcus <(b) (6)> Macone, Erin <(b) (6)>
Tountas, Karen (FNIH) [T] <(b) (6)> Wachtel, Jonathan <(b) (6)> Elizabeth Kim
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Butcher, Tina
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T]
<(b) (6)> Wung, Peter /US <(b) (6)> Qashu, Felicia (NIH/OD) [E]

< (b) (6) Stratton, Benjamin < (b) (6)
Subject: Re: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Good morning all:

It would seem that our active control arm had been identified. Should we get in the queue with Gilead sooner rather than later - or have we already reached out to them?

S

From: "Adam, Stacey (FNIH) [T]" < (b) (6)
Date: Thursday, April 23, 2020 at 8:31:00 PM
To: "Bozzette, Sam (NIH/NCATS) [E]" (b) (6), "Butterton, Joan" (b) (6),
"Collins, Sylva (FDA/CDER)" (b) (6), ">, "Judy Currier" (b) (6), ">, "De Claro, R.
Angelo (FDA/CDER)" (b) (6), "Mark Eisner" (b) (6), "Keith Gottesdiener"
(b) (6), "Eric Hughes" (b) (6), "LaVange, Lisa M"
< (b) (6), "Elliott Levy" (b) (6), "Sandeep Menon" (b) (6)
"Amanda Peppercorn" (b) (6), ">, "Proschan, Michael (NIH/NIAID) [E]"
(b) (6), "Read, Sarah (NIH/NIAID) [E]" (b) (6), "Amanda Peppercorn"
< (b) (6), "Price, Dionne (FDA/CDER)" < (b) (6), "Rubin, Daniel B.
(FDA/CDER)" < (b) (6), "Shen, Yuan Li (FDA/CDER)" (b) (6), ">, "Farley, John
(FDA/CDER)" (b) (6), "Goff, David (NIH/NHLBI) [E]" (b) (6), ">, "Vincent, Michael"
(b) (6)
Cc: "Mary Biggs" < (b) (6), "Demarcus" < (b) (6), "Macone, Er n"
(b) (6), "Tountas, Karen (FNIH) [T]" (b) (6), "Wachtel, Jonathan"
(b) (6), "Elizabeth Kim" (b) (6), "Parker, Ashley (NIH/OD) [E]"
< (b) (6), "Butcher, Tina" (b) (6), "Wholley, David (FNIH) [T]"
(b) (6), "Melencio, Cheryl (FNIH) [T]" (b) (6), "Wung, Peter /US"
< (b) (6), "Qashu, Felicia (NIH/OD) [E]" < (b) (6), "Stratton, Benjamin"
(b) (6), ">
Subject: RE: ACTIV TX-Clinical Master Protocol Subgroup Meeting #7

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for tomorrow's meeting.

1. Agenda
2. Slides for discussion updated with the decisions from today
3. A useful resource about current standard clinical treatment guidelines from the front lines for COVID. This may be a useful resource in selecting how to do minimal data collection and trying to understand SOC.

Please let me know if you have questions or other things you think would be helpful for the group to review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: (b) (6) | Mobile: (b) (6) |

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(b) (6)

From: Santos, Michael (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 2/12/2021 8:35:48 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
(b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd];
(b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad33f983de-aarvin.stan];
(b) (6) Cavalieri, Marco [(b) (6) : (b) (6) : mmdavis
[(b) (6) (b) (6) Greg Glenn [(b) (6)
(b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002 mc]; hotez@bcm.edu;
(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VR) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aeb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fdb4598a57b423d484dcf9f-offit.email]; HSchuite@its.nj.com; Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se];
(b) (6) (b) (6) Tal Zaks [(b) (6)]; Beth Bell
(b) (6) [(b) (6)
CC: Tolman, Brett [(b) (6) (b) (6) Hopps, Markay [(b) (6)
Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr];
(b) (6) Jeneffer Haynes [(b) (6)]; (b) (6)
(b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj];
(b) (6) Isabel Ramsey [(b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Embry, Alan (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=882a18a10a134c49acac21cb83fd599d-embrya]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeling]; Dieffenbach, Carl (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94acc37973d346fa98dfe16cd1bf7013-cdieffenba]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboise]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Lumsden, Joanne
 (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=1be900c2388d41f48e3f2cbcb2fed349-lumsdenjm]; Eric Hughes
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Kurilla, Michael
 (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
 (b) (6) Paul Gillard | (b) (6) François P Roman | (b) (6)
 Gonzalez Lopez, Antonio | (b) (6) Hamilton, Holli (OS/ASPR/BARDA)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli Hamil]; Modjarrad, Kayvon CIV
 USARMY MEDCOM WRAIR (USA) | (b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.som];
 Martin, Stacey (CDC/DDID/NCEZID/DVBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffe35bbdbfbfd495f97712313bedcaecc-ZMT0]; McNamara, Lucy Alexandra
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=94d2e362b03243568fa31c3d23550095-xdf4]; Goldstein, Jason
 (CDC/DDID/NCEZID/DSR) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2f414dc157843bba7369a63dfde3e5e-fex0]; Schrag, Stephanie
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Sotir, Mark
 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5b3ddfd786c14559802df76dd7b6bc49-mps6]; Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
 | (b) (6)]; 'Wachtel, Jonathan' (b) (6)]; Stratton, Benjamin
 | (b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso],
 (b) (6) (b) (6) Bethany Stokes
 | (b) (6) Kathleen Callahan | (b) (6) Molloy, Delia (DPH)
 | (b) (6) Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Filip Dubovsky
 | (b) (6)]; Jacqueline Miller | (b) (6) Antonio Lanzavecchia
 | (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Harris, Rebecca /SG
 | (b) (6) Vivek Shinde | (b) (6) Cohen, Myron
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Criffield, Rob n R.
 | (b) (6) Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; FNIH
 | (b) (6) Barton Haynes, M.D. | (b) (6) Michael, Nelson
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=05b9ca6b24634974b7aeb3fcaead1623-nmichael.hi]; Gilbert PhD, Peter B
 | (b) (6) pennym | (b) (6) Alex Sigal | (b) (6) Ho, David
 D. (b) (6) Offit, Paul | (b) (6) Randy Hyer | (b) (6) Adam
 Bloomfield | (b) (6) Gale Smith | (b) (6) Florence, Clint (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295f-florencewc];

(b) (6) (b) (6) Wan, Kanny (NIH/NCATS) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b478497d58dc46e4b3cfdea14f17ecd1-wankk]; RZa (b) (6)
 Desrosiers, Betsy [(b) (6) Bloom PhD, Jesse D (b) (6) Christopher
 Murray [(b) (6)

Subject: ACTIV Vaccines Working Group meeting
Attachments: Agendas and notes for ACTIV Vaccines Working Group meetings
Location: <https://nih.zoomgov.com/j/1614753565?pwd=YnBaUFIMdml6ZDZsR1NSM01EbkRrdz09>

Start: 2/18/2021 7:00:00 PM
End: 2/18/2021 8:00:00 PM
Show Time As: Busy

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
(b) (6) (b) (6) Cavaleri Marco; (b) (6)
(b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit Paul; (b) (6) Seals, Jonathan
(OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C]; Johnson Maureen
(NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
(b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
Ashley (NIH/OD) [E]; Embry, Alan (NIH/NIAID) [E]; Erbeling, Emily (NIH/NIAID) [E]; Dieffenbach, Carl (NIH/NIAID) [E];
Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FN H) [T];
Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James,
Stephanie (FN H) [T]; Colvis, Christine (NIH/NCATS) [E]; Lumsden, Joanne (NIH/NCATS) [C]. Desrosiers, Betsy; Hughes,
Eric; Kunlia Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul Gillard; François P Roman;
Gonzalez Lopez, Antonio; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR
(USA); Kathleen Neuzil; Martin, Stacey (CDC/DDID/NCEZID/DVBD); McNamara, Lucy Alexandra
(CDC/DDID/NCIRD/DBD); Goldstein, Jason (CDC/DDID/NCEZID/DSR); Schrag, Stephanie (CDC/DDID/NCIRD/DBD);
Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Sotir, Mark (CDC/DDID/NCIRD/DVD); Thornburg, Natalie
(CDC/DDID/NCIRD/DVD), Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin, Anderson, Margaret;
(b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Molloy,
Delia (DPH); Wood, Gretchen (N-H/OD) [E]; Filip Dubovsky; Jacqueline Miller; Antonio Lanzavecchia; Ann Arvin;
Harris, Rebecca /SG; Vivek Shinde; Cohen, Myron; Criffied, Robin R.; Marovich, Mary (NIH/N AID) [E]; FNIH; Barton
Haynes, M.D; Nelson Michael; Gilbert PhD, Peter B; Bloom PhD, Jesse D; (b) (6) Christopher Murray;
pennym; Alex Sigal; Ho, David D.; Offit, Paul; Randy Hyer; Adam Broomfield; Gale Smith; Florence, Clint (NIH/NIAID)
[E]; (b) (6) (b) (6) Wan, Kanny (NIH/NCATS) [C];
(b) (6)

<https://nih.zoomgov> (b) (6)

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Passcode: (b) (6)
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US (San Jose)
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US

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(US West)

(US East)

Meeting ID: (b) (6)

Passcode: (b) (6)

From: Eakin, Ann (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DAFBA298C194F9D9BC13C54FE0CF29A-EAKINAE]
Sent: 7/2/2020 1:02:54 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli (b) (6); Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel (b) (6); Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6); Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike (b) (6); Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael (b) (6); Keith Gottesdiener (b) (6); Elliott Levy (b) (6); Wung, Peter /US (b) (6); Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner (b) (6); Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; (b) (6); Rose Li (b) (6); Mark Krystal (b) (6); Prabhavathi Fernandes (b) (6); Diamond, Michael (b) (6); Sanderson, Philip (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee2d44e63f2645708a3beb2ea1b280a1-sandersonpe]; Tressler, Randal (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c1978dd53134e13ac736758e8b8756f-tressler]; (b) (6); Dana Carluccio (b) (6); Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Sumit Chanda (b) (6); Rich Colunno (b) (6); Fisher, Robert (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=706cb01f58ef4042aecc4de5ab72ec1-Robert.Fish]
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Salathin, Carla (b) (6); (b) (6); (b) (6); Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

I can make 3:30 but not 3.

From: Adam, Stacey (FNIH) [T] <(b) (6)>

Sent: Wednesday, July 1, 2020 8:59:48 PM

To: Eric Hughes <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Ruxandra Draghia-

Akli < (b) (6) Mellors, John W < (b) (6) Naimish Patel < (b) (6) Colvis,
 Christine (NIH/NCATS) [E] < (b) (6) Young, John < (b) (6) Stein, Peter
 (FDA/CDER) < (b) (6) Poole, Mike < (b) (6) Buchman, Tim
 (OS/ASPR/BARDA) (CTR) < (b) (6) Vincent, Michael < (b) (6) Keith
 Gottesdiener < (b) (6) Elliott Levy < (b) (6) Wung, Peter /US
 < (b) (6) Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) Higgs, Elizabeth
 (NIH/NIAID) [E] < (b) (6) Carlos O Garner < (b) (6) Goff, David (NIH/NHLBI) [E]
 < (b) (6) Alvarez, Rosa Maria < (b) (6) (b) (6)
 < (b) (6) Rose Li < (b) (6) Mark Krystal < (b) (6)
 Prabhavathi Fernandes < (b) (6) Diamond, Michael < (b) (6) Sanderson,
 Philip (NIH/NCATS) [E] < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Tressler,
 Randall (NIH/NIAID) [E] < (b) (6) < (b) (6)
 Eakin, Ann (NIH/NIAID) [E] < (b) (6) Young, John < (b) (6) Mellors, John W
 < (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) Dana Carluccio
 < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Sumit Chanda
 < (b) (6) Colvis, Christine (NIH/NCATS) [E] < (b) (6) (b) (6)
 < (b) (6) Draghia Akli, Ruxandra [JRDU] < (b) (6) Hughes, Eric
 < (b) (6) < (b) (6) Rich Colonno
 < (b) (6) Fisher, Robert (FDA/OC) < (b) (6)
 Cc: Chen, Helen Q. < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Alvarez, Rosa Maria
 < (b) (6) Salathin, Carla < (b) (6) (b) (6) < (b) (6)
 (b) (6) < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6)

Subject: RE: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX-Clinical Agent Prioritization Subgroup and Antiviral Subteam,

While I could not get quorum for the 12-1pm slot for our discussion tomorrow, many of you said you could be available after 3pm. Therefore, could you all let me know if 3-4pm ET tomorrow would work for you to meet?

Thanks,
Stacey

Stacey J. Adam, PhD
 Director, Cancer
 Research Partnerships
 Direct: (b) (6) Mobile: (b) (6)

From: Adam, Stacey (FNIH) [T]

Sent: Tuesday, June 30, 2020 10:55 PM

To: Eric Hughes < (b) (6) Read, Sarah (NIH/NIAID) [E] < (b) (6) Ruxandra Draghia-
 Akli < (b) (6) John Mellors < (b) (6) Naimish Patel < (b) (6) Colvis,
 Christine (NIH/NCATS) [E] < (b) (6) Young, John < (b) (6) Stein, Peter
 (FDA/CDER) < (b) (6) Poole, Mike < (b) (6) Buchman, Tim
 (OS/ASPR/BARDA) (CTR) < (b) (6) Vincent, Michael < (b) (6) Keith
 Gottesdiener < (b) (6) Elliott Levy < (b) (6) Wung, Peter /US
 < (b) (6) Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) Higgs, Elizabeth
 (NIH/NIAID) [E] < (b) (6) Carlos O Garner < (b) (6) Goff, David (NIH/NHLBI) [E]
 < (b) (6)
Cc: Chen, Helen Q. < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Alvarez, Rosa Maria
 < (b) (6) Salathin, Carla < (b) (6) (b) (6) (b) (6) Parker,
 Ashley (NIH/OD) [E] < (b) (6)

Subject: Scheduling an ACT V TX-Clinical Agent Prioritization Subgroup Meeting

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

We would like to have a meeting on Thursday with this team and the Antiviral review subteam to discuss and finalize the Antiviral Subgroup's selections from this latest Wave of prioritization.

Please let me know if you would be able to attend this meeting from 12-1pm ET.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: (b) (6) Mobile: (b) (6)
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/20/2020 2:10:26 AM
To: Eric Hughes | (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Na mish Patel | (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike | (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim Buchman]; Vincent, Michael | (b) (6) Keith Gottesdiener | (b) (6) Elliott Levy | (b) (6) Wung, Peter /US | (b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner | (b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Elizabeth Kim | (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria | (b) (6) Salathin, Carla | (b) (6) (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon | (b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]; Rose Li Central Account | (b) (6)
Subject: Initia Follow-up to ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #11
Attachments: ACTIV_Therapeutics-Clinical_AP Sub-Group Meeting 19May2020_Key Takeaways.pdf

Dear ACTIV TX-Clinical Agent Prioritization Subgroup,

Thank you all for a productive meeting today. I am glad we were able to finalize the RFI/Survey for the companies. We are well into building the REDCap data capture platform. We will share with you all the link once it is done.

Thank you as well for your feedback on the mAbs. Many of you have already gotten back to me with nominations for the committee, so I will like follow up individually with those who have expressed interest and if we do not fully meet our 6-8, I will then reach out again to the broader group.

For your reference, please find attached the high level notes for the meeting. The formal complete summary will be sent tomorrow.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer

APAR0000005367-2517546

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 [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Nayak, Seema (NIH/NIAID) [E]
 [(b) (6) Qashu, Felicia (NIH/OD) [E] [(b) (6) Sizemore, Christine (NIH/FIC) [E]
 [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Mensah, George (NIH/NHLBI) [E]
 [(b) (6) Weinmann, Gail (NIH/NHLBI) [E] [(b) (6) Payton, Manizhe
 (NIH/NIAID) [E] [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
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 [(b) (6) Bascles, Lionel [(b) (6) Vincent, Mike
 [(b) (6) Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative
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 (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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CC: Melencio, Cheryl (FNIH) [T] [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [(b) (6) Hill, Zoe
 (NIH/NHLBI) [C] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Gonzalez, Nina
 [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Menetski, Joseph (FNIH) [T]
 [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Wholley, David (FNIH) [T]
 [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI)
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [(b) (6) Ferguson, Sue [(b) (6) Kenny, Dermot [(b) (6)
 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Nancy [(b) (6)]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
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 [(b) (6) Mueller-Reichenstein, Petra [(b) (6) Quadros, Nora
 [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adam, Stacey (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret

(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras], Carluccio, Dana
 (b) (6) Heaton, Penny (b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose
 (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tuveson, Nancy
 (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric
 (b) (6) Jansen, Kathrin (b) (6) i]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
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Attachments: Clinical Trial Capacity Working Group Meeting Agenda 05292020 pdf

Location: <https://fnih.zoom.us> (b) (6)

Start: 5/29/2020 1:00:00 PM

End: 5/29/2020 2:00:00 PM

Recurrence: (none)

Required Attendees: Garner, Carlos; Bascles, Lionel; Vincent, Mike; Payton, Manzone; Cohen, Myron; Corey, Larry; Davey, Victoria; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurila, Mike; Nayak, Seema (NIH/NIAID) [E]; Qashu, Felicia; Resnansky, Laura; Sizemore, Christine (NIH/FIC) [E]; Srinivasan, Badhri; Stein, Peter (FDA/CDER); Wachtel, Jonathan; Mensah, George; Weinmann, Gail

Optional Attendees: Culp, Michelle (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Kublin MD, MPH, James; Ferguson, Sue; Kenny, Dermot; Gonzalez, Nina; Griffith, Robin; Hamilton, Nancy; Meencio, Cheryl (FNIH) [T]; Minich, Beth; Mueller-Reichenstein, Petra; Quadros, Nora; Rebecca (NIH/NCATS) Katz [E] (b) (6) Zoe (NIH/NHLBI) Hill [C]
 (b) (6) Adam, Stacey (FNIH) [T]; Anderson, Margaret; Ashley (NIH/OD) Parker [E]
 (b) (6) Carluccio, Dana; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John

Colleagues – Attaching the agenda for the call. Best, Karen

Dear Clinical Trial Capacity WG members, This will extend our full working group calls through the end of May We'll assess the need for further meetings at the end of the month. Many thanks for your participation! Karen

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Sent: 5/14/2020 12:13:17 AM
To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesdener, Keith | (b) (6) Hughes, Eric | (b) (6) Judy Currier
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6) Garner, Carl | (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Burgess, Timothy | (b) (6) Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]
CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy | (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John | (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Li Central Account [(b) (6) Anderson, Margaret [(b) (6) Lucas
 Smalldon [(b) (6) Stratton, Benjamin [(b) (6)
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Goff, David (NIH/NHLBI) [E]
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Subject: ACTIV TX-Clinical Working Group #6
Attachments: FDA Guidance on COVID Trials.pdf; ACTIV Therapeutics-Clinical Full Working Group 14May2020 Meeting Guide.pdf
Location: https://fnih.zoom. (b) (6)

Start: 5/14/2020 6:00:00 PM
End: 5/14/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]
Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Car a; Tountas Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose L. Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] ((b) (6)

Dear TX-Clinical Working Group,

Please find attached the slides for tomorrow's call to help facilitate our report outs from both groups. If you have any additions or amendments to propose, please send them to me.

The co-chairs will be updating the group on the ACTIV Executive Committee's feedback and promised actions in response to our letter. This will include some immediate next steps for our group on the mAbs master protocol discussion. Thank you all once again for this feedback to the leadership. It was well received, and it looks like will elicit immediate action on some of the requests.

In addition, please find attached the FDA Guidance for COVID-19 trials that was released today. You can also find it at this link if needed: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention>

Looking forward to tomorrow's call.

Thanks,
Stacey

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CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: Fwd: Agenda and materials for the Protective Immune Responses Sub-Group meeting
Attachments: image001.jpg; ATT00001.htm; image002.jpg; ATT00002.htm; image003.jpg; ATT00003.htm; image004.jpg; ATT00004.htm; Assay WG Tracker Updated 6-4.xlsx; ATT00005.htm

Forwarding the information for the vaccines subgroup meeting taking place at 2:30pm today "inter-comparability of immunogenicity assays and centralized labs" and follow up conversations with Janet next week on assay development by vaccine developers — FYI.

Seems there are already POCs for NIAID.

Best,
Ashley

Begin forwarded message:

From: "Santos, Michael (FNIH) [T]" <(b) (6)>
Date: June 9, 2020 at 10:59:53 PM EDT
To: "(b) (6)" <(b) (6)>
" (b) (6)" <(b) (6)>
<(b) (6)> "Gruber, Marion (FDA/CBER)" <(b) (6)>
<(b) (6)> "Marks, Peter (FDA/CBER)" <(b) (6)>
, "Arvin, Aron" <(b) (6)>
(b) (6) Nelson Michael (b) (6) >, "Bett, Andrew J" <(b) (6)>
(b) (6) "Gilbert PhD, Peter B" (b) (6) "Kathleen Neuzil" <(b) (6)>
(b) (6) , "Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA)" <(b) (6)>
<(b) (6)> "Thornburg, Natalie (CDC/DDID/NCIRD/DVD)" <(b) (6)>
Greg Glenn (b) (6) Cavaleri Marco (b) (6) "Kelly, Beth" <(b) (6)>
(b) (6)
Cc: "Tolman, Brett" <bto: (b) (6)> * (b) (6)
(b) (6)
(b) (6) >, Jeneffer Haynes (b) (6)
"Menetski, Joseph (FNIH) [T]" (b) (6) >, "Alvarez, Rosa Maria" (b) (6)
"Wholley, David (FNIH) [T]" <(b) (6)> "Parker, Ashley (NIH/OD) [E]" <(b) (6)>
(b) (6) , Brian Rosen (b) (6) . Cheryl Keech (b) (6)
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting at 2:30pm ET (11:30am PT / 6:30pm CEST).

Last week we were fortunate to have Marco Cavaleri present and lead a discussion on EMA regulatory pathways. Development of a table of those pathways analogous to the table developed for FDA pathways is underway.

At this meeting we will return to the topics from two weeks ago: (1) reaching out to collect information on potential signals of human immunity and (2) inter-comparability of immunogenicity assays and centralized labs.

Since that meeting Ann and Mark Davis discussed the first topic, and reached out to Dan Rotrosen (Director of the Division of Allergy, Immunology, and Transplantation at NIAID). He is unfortunately unable to join this meeting, but we will discuss the categories of information we would like to collect and the potential process for doing so.

On the second topic, we reached out to Janet Lathey (NIAID) and Ashley Smith (BARDA), who co-lead a USG working group on assay development. They kindly provided the attached draft list of assays under development through USG mechanisms. Janet will join our meeting next week to discuss the assays and engagement by vaccine developers with the labs running them.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, June 3, 2020 11:30 PM
Subject: Notes from yesterday's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting, and particular thanks to Marco for the excellent presentation and discussion.

Meeting notes are attached, with the meeting materials are embedded. The key action item is developing a table of EMA pathways analogous to the one that we previously developed with Marion's input and review for FDA pathways.

Please reach out with any additions or edits to the notes, questions, or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Monday, June 1, 2020 1:04 PM
Subject: Agenda and materials for the Protective Immune Responses Sub-Group meeting tomorrow (Tuesday)

Dear Protective Immune Responses Sub-Group members,

We're looking forward to our meeting tomorrow (Tuesday) at 8am ET (5am PT / 2pm CEST). We are very sorry for the extremely early start PT.

The main agenda item is to discuss EMA and member state regulatory pathways to vaccine use and approval. Marco will lead the discussion. He previously shared a set of presentation slides (re-attached here). We are also re-attaching the table on FDA pathways that we circulated previously.

Please let us know if you have any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Thursday, May 28, 2020 12:57 PM
Subject: Notes and next steps from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Thanks for your participation in yesterday's meeting. Notes are attached.

There were two key areas for next steps that we identified in the meeting:

- Potential signals of human immunity:
 - Develop specifics of what we are looking for from immunology research
 - Ask the WG and other contacts for suggestions of researchers/organizations worth reaching out to
 - Reach out and collect information and contacts to engage with the WG (in presentations or other formats)
- Inter-comparability of immunogenicity assays / centralized labs
 - Reach out to NIAID to learn more about planned centralized lab capabilities and timing

Ann kindly followed up with an initial set of recommendations for the first area. We'll be following up to develop the list of information that we'd like to gather and to discuss how to prioritize whom we reach out to. We'll reach out to NIAID and report back on the second area.

We think these topics will form the basis for future discussions, but we are also trying to schedule a meeting for a time when we can have a discussion about the EMA regulatory pathways with Marco, to complement the conversations we have had on FDA pathways. We hope to have an invite for that out soon.

As always, please reach out with any additional input on the notes, questions, or suggestions for future directions for this group.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 11:42 PM
Subject: Agenda for the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

We're looking forward to today's (Wednesday) meeting, at 9am ET (6am PT / 3pm CEST).

Since our last meeting, Marco kindly shared the attached document on EMA and member state regulatory pathways for vaccine use and approval. Unfortunately Marco won't be able to join this meeting, but has offered to discuss the EMA pathways at a future meeting.

Our recent meetings have focused primarily on understanding regulatory pathways for vaccine use and approval, and the types of evidence that factor into regulatory decisions for different pathways, with two presentations on upcoming sources of evidence (NIAID NHP challenge studies using sera/IgG/mAbs and CDC immunological studies). A key goal of this group is to facilitate vaccine developers to generate evidence that can support evaluation of vaccine efficacy. For today's meeting, we plan to discuss the different categories of evidence and identify priorities for ACTIV to engage to be supportive.

We look forward to the discussion. If you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 26, 2020 12:19 AM
Subject: Notes from the Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached notes and materials from our meeting last week. Thanks again to Donna and Natalie for presenting, and as always to Marion for her contributions to the regulatory pathways during the meeting and subsequently.

We will be in touch again soon regarding this week's meeting. Feel free to reach out any time with questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Tuesday, May 19, 2020 8:56 AM
Subject: Agenda and Materials for today's Protective Immune Responses Sub-Group meeting

Dear Protective Immune Responses Sub-Group members,

Please find attached two documents for today's Protective Immune Responses Sub-Group meeting (2pm ET / 11am PT / 8pm CEST):

- An updated table of pathways to vaccine use
- Notes from the last Sub-Group meeting (with my apologies for the delay)

For today's meeting, the agenda items are:

- Discussion of the updated pathways table and next steps
- An overview of the CDC's serology activities by Natalie

We're looking forward to the discussion today. As always, if you are unable to attend please feel free to send comments or questions before or after the meeting.

Best regards,
Brett and Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

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From: Tountas Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/19/2020 1:16:52 AM
To: Vincent, Mike [(b) (6) : Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Bascles, Lionel [(b) (6)]; Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey, Larry [(b) (6) Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickens]; Doroshow, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshoj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Nayak, Seema (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payton, Manizhe (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Resnansky, Laura [(b) (6) Srinivasan, Badhri [(b) (6) Wachtel, Jonathan [(b) (6) Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]
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Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da];
Jintanat Ananworanich (b) (6)

Subject: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Attachments: Clinical Trial Capacity Working Group Meeting Agenda 05192020.pdf
Location: <https://zoom> (b) (6)

Start: 5/19/2020 1:00:00 PM
End: 5/19/2020 2:00:00 PM
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Recurrence: Weekly
every Tuesday and Friday from 9:00 AM to 10:00 AM
Required Attendees: Vincent, Mike; Stein, Peter (FDA/CDER); Bascles, Lionel; Cohen, Myron; Corey, Larry; Desrosiers, Betsy; Dickens, Jim (NIH/NCATS) [C]; Doroshov, James (NIH/NCI) [E]; Goff, David (NIH/NHLBI) [E]; Kurilla, Mike; Nayak, Seema (NIH/NIAID) [E]; Parker, Ashley (NIH/OD) [E]; Payton, Manzine; Resnansky, Laura; Srinivasan, Badhri; Wachtel, Jonathan; Qashu, Felicia
Optional Attendees: Sizemore, Christine (NIH/FIC) [E]; Kenny, Dermot; Weinmann, Gai (NIH/NHLBI) [E]; Garner, Carlos; Colvis, Christine (NIH/NCATS) [E]; Hughes, Eric; Jansen, Kathrin; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Young, John; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Carluccio, Dana; Cheryl (FNIH) Melencio [T] (b) (6)
Francis Collins, Gonzalez, Nina; Heaton, Penny; James, Stephanie; Li, Rose; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH); Tuveson, Nancy; Wholley, David (FNIH) [T]; Criffield, Robin; Hamilton, Nancy; Minnich, Beth; Rebecca (NIH/NCATS) Katz [E] (b) (6) Stratton, Benjamin; Tolman, Brett; Davey, Victoria; Jintanat Ananworanich

Dear Colleagues, We have an interesting agenda (attached) for this call and look forward to the discussion surrounding each topic! Best, Karen

ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines

Dear Clinical Trial Capacity Working Group members,

In anticipation of this working group making rapid progress on identified action items and other activities, the co-chairs have agreed that it will be important to hold twice-weekly calls to evaluate progress made by each subgroup, to identify areas of need, and to determine next steps. We ask that you make every effort possible to join each of these meetings, but understand that at times you may have competing priorities. To place a hold on your calendar, please accept this meeting invite with a response, later you can decline an individual meeting if you have a conflict.

An agenda and other meeting materials, as needed, will be distributed prior to each call.

With best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

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CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6)]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: ACTIV TX-Clinical Therapeutics Master Protocol Subgroup #14
Location: <https://fnih.zoom.us/> (b) (6)
Start: 5/8/2020 5:00:00 PM
End: 5/8/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterton; Collins, Sylvia (FDA/CDER); Judy Carrier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.

Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]

Stacey Adam is inviting you to a scheduled Zoom meeting.

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Meeting ID: (b) (6)

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(b) (6)

From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]
Sent: 5/14/2020 2:52:17 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-MarksP.fda]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
CC: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]
Subject: RE: ChAdOx1

I don't sense that other companies have any major concerns. Merck, JJ, Sanofi – all part of good productive discussion. But Pfizer's two representatives spoke more than all the other companies combined for this particular hour call.

I'd ask Dough to give his perspective here.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 10:32 AM
To: Mascola, John (NIH/VRC) [E] <(b) (6)>; Marks, Peter (FDA/CBER) <(b) (6)>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>; Lowy, Douglas (NIH/NCI) [E] <(b) (6)>
Subject: RE: ChAdOx1

Thanks for this input, John and Peter.

It's too bad that Pfizer is dominating the discussion about the DSMB, when they apparently don't intend to take part in the harmonized master protocol anyway. Are there other companies represented on the Vaccines WG who might feel differently? I'm looping in Doug (and should have done so earlier, sorry!).

Francis

From: Mascola, John (NIH/VRC) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 9:03 AM
To: Marks, Peter (FDA/CBER) <(b) (6)>; Collins, Francis (NIH/OD) [E] <(b) (6)>; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: ChAdOx1

Francis - we did make good progress on ACTIV Vaccine WG. Yesterday on the vaccine clinical trials subgroup, we presented the harmonized protocol approach and high level details of phase 3 design. There was good input on both and general agreement, with some useful recommendations on efficient ways to conduct phase 3.

One issues is that the Pfizer representative on the subgroup, both Kathrin Jansen (who is co-chair of Vaccines WG), and Bill Gruber (Pfizer Senior VP for R&D) took turns articulating their view that large Pharma companies like theirs prefer not to work with USG and it would just slow them down. When we asked for suggestions for DSMB, Kathrin said she did not agree that we should ask for nominations – because this issue required more discussion – mainly because Pfizer has no interest in this. Doug Lowy was on the call, so may be useful to get his perspective.

John

From: Marks, Peter (b) (6)
Sent: Thursday, May 14, 2020 6:23 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Mascola, John (NIH/VRC) [E] (b) (6) >; Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Cc: Fauci, Anthony (NIH/NIAID) [E] (b) (6) >; Wholley, David (FNIH) [T] (b) (6) >; Tabak, Lawrence (NIH/OD) [E] (b) (6) Parker, Ashley (NIH/OD) [E] (b) (6)
Subject: RE: ChAdOx1

Dear Francis,

We had made good progress with the Oxford AZ team on the clinical end before the contracting period began. From my last conversation with the AZ clinical team they were on board with the USG concept of a large phase 3 trial, potentially as part of a master protocol if the timing was right. Their major issue was getting moving rapidly.

Among other things, Tony, John and I discussed the concept that (b) (5)
(b) (5)

Later today I will be speaking with John again about this merged concept. After giving it very careful consideration, though it certainly involves significant extra work in protocol development and logistic planning, (b) (4). (b) (5)
(b) (4). (b) (5)

(b) (4). (b) (5) Happy to discuss further.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Thursday, May 14, 2020 5:38 AM
To: Mascola, John R (NIH) (b) (6) >; Lane, Henry C (NIH) (b) (6) Marks, Peter (b) (6)
Cc: Fauci, Anthony S (NIH) (b) (6) ; Wholley, David N (NIH) (b) (6) ; Tabak, Lawrence A (NIH) (b) (6) >; Parker, Ashley S (NIH) (b) (6)
Subject: ChAdOx1

Gentlemen:

I need to know the update on where we are with Oxford, A Z, and ChAdOx1. I see there's a BARDA WebEx at 5 pm, and I have a rescheduled phone call this morning with John Bell. I'd like to be as useful as possible in making a plan that includes this vaccine program as part of the harmonized master protocol. Advice about how to use the call with John Bell most effectively would be most welcome!

And did the Vaccines WG make good progress yesterday on the details of the harmonized master protocol? Did they agree in principle to a single DSMB?

Thanks, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/9/2020 5:28:03 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [(b) (6) Bright, Rick [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Disbrow, Gary (OS/ASPR/BARDA) [(b) (6) Dolsten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAID) [E] [(b) (6) James, Stephanie (FNIH) [T] [(b) (6) Lane, Cliff (NIH/NIAID) [E] [(b) (6) Marks, Peter (FDA/CBER) [(b) (6) Marston, Hilary (NIH/NIAID) [E] [(b) (6) Mascola, John (NIH/VRC) [E] [(b) (6) Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [(b) (6) Pao, William [(b) (6) Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plump, Andy [(b) (6) Rasi, Guido [(b) (6) Reed, John [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [(b) (6) Stein, Peter (FDA/CDER) [(b) (6) Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Virgin, Skip [(b) (6) Woodcock, Janet (FDA/CDER) [(b) (6) Young, John [(b) (6) Parker, Ashley (NIH/OD) [E] [(b) (6) Gladman, Jordan (NIH/OD) [E] [(b) (6) Colvis, Christine (NIH/NCATS) [E] [(b) (6) Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Hudson, Thomas [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [(b) (6) Lowy, Douglas (NCI) [(b) (6) Read, Sarah (NIH/NIAID) [E] [(b) (6) Johnson, Robert (OS/ASPR/BARDA) [(b) (6) Pandya, Hitesh [(b) (6) Skovronsky, Daniel [(b) (6) Freire, Maria (FNIH) [T] [(b) (6) Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Pangalos, Mene [(b) (6)
CC: Barasch, Kimberly (NIH/NIAID) [C] [(b) (6) Conrad, Patricia (NIH/NIAID) [E] [(b) (6) Hoffstetter, Renata (FNIH) [T] [(b) (6) Iberdemaj, Vaide [(b) (6) Melencio, Cheryl (FNIH) [T] [(b) (6) Protasiewicz, Ann [(b) (6)]; Thomas, Ashley (FDA/CDER) [(b) (6) Wood, Gretchen (NIH/OD) [E] [(b) (6) Burrus-Shaw, Cyndi (NIH/OD) [E] [(b) (6) Simon, Dina (NIH/OD) [C] [(b) (6) Lagos, Enrique (NIH/NCATS) [E] [(b) (6)]; McManus, Ayanna (NIH/OD) [E] [(b) (6) Adam, Stacey (FNIH) [T] [(b) (6) Li, Rose [(b) (6) Tountas, Karen (FNIH) [T] [(b) (6) Zottoli, Jessica [(b) (6) Gonzalez, Nina [(b) (6) Anderson, Margaret [(b) (6) Robert Plenge [(b) (6) Stratton, Ben [(b) (6) Alvarez, Rosa [(b) (6) Kim, Elizabeth [(b) (6) Wachtel, Jonathan [(b) (6) Tolman, Brett [(b) (6) Mammen, Mathai [JUCUS] [(b) (6) Lowy, Douglas (NIH/NCI) [E] [(b) (6) Giorgi Sara [(b) (6) FNIH Central Account [(b) (6) Lucas Smalldon [(b) (6) Tierney, Julia (FDA/CBER) [(b) (6) Sepulveda, Dorina (FNIH) [T] [(b) (6)
Subject: ACTIV response partnership leadership team meeting #2
Location: <https://zoom.us>, (b) (6)
Start: 4/22/2020 2:00:00 PM
End: 4/22/2020 3:00:00 PM
Show Time As. Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bright, Rick; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; James, Stephanie (FNIH) [T]; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Covis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Hudson, Thomas; Kurila, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Johnson, Robert (OS/ASPR/BARDA); Pandya, Hitesh; Skovronsky, Daniel;

(b) (6) (b) (6) Freire, Maria (FNIH) [T]

Optional Attendees: Barasch, Kimberly (NIH/NIAID) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Li, Rose; Tountas, Karen (FNIH) [T]; Zottoli, Jessica; Gonzalez, Nina; Anderson, Margaret; Robert Plenge, Stratton, Ben; Alvarez, Rosa; Kim, Elizabeth; Wachtel, Jonathan; Tolman, Brett; Mammen, Mathai [JJCUS]; Lowy, Douglas (NIH/NCI) [E]; Giorgi Sara; FNIH Central Account; Lucas Smalldon; Tierney, Julia; Sepulveda, Dorina (FNIH) [T]

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Find your local number: <https://zoom.us> (b) (6)

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 4/15/2020 9:27:45 PM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; (b) (6) (b) (6) (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; hotez@bcm.edu; (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56fde4598a57b423d484dcf9f-offit.email]; HSchulte@its.nj.com; Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6)
CC: Tolman, Brett [(b) (6)]; (b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) (b) (6) (b) (6) (b) (6) Corrigan, Angela (NIH/VRC) [F] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83998896b0ce4d23a9e481d87568d20f-corriganar]; (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy [(b) (6) Hughes, Eric [(b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; (b) (6) (b) (6) Wachtel, Jonathan [(b) (6)]; Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001a98d300d14b20b18c01181eb843e0-Arvinam.Sta]; Anderson, Margaret

(b) (6) Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex>. (b) (6)

Start: 4/20/2020 1:00:00 PM

End: 4/20/2020 2:00:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; (b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Haynes, Barton; (b) (6) (b) (6) (b) (6) Marks, Peter (FDA/CBER);
Mascola, John (N H/VRC) [E]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Offit, Paul; (b) (6) Seals,
Jonathan (OS/ASPR/BARDA); (b) (6)
Optional Attendees: Tolman, Brett; (b) (6) Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen (N H/NC) [E];
(b) (6) (b) (6) (b) (6) (b) (6)
Corrigan, Angela (NIH/VRC) [F]; (b) (6) Parker, Ashley (NIH/OD) [E]; Collins, Francis
(NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Adam, Stacey
(FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; Desrosiers,
Betsy; Hughes, Eric; Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Gonzalez, N na;
(b) (6) (b) (6) Wachtel, Jonathan; Ann Arvin; Anderson,
Margaret; Marston, Hilary (NIH/NIAID) [E]

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/29/2020 11:40:46 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Gonzalez, Nina [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: Key messages re. immunomodulators for slides for Moncef meeting tomorrow 5/30

Have seen and offered a few changes to the complete slide deck. They should be coming back to you as soon as Deloitte makes the changes.

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Friday, May 29, 2020 5:59 PM
To: Wholley, David (FNIH) [T] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gonzalez, Nina <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: RE: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Hi all,

I have received information from Amy Patterson about the anticoagulant trial, and I'd like to have that incorporated into the slide set that Deloitte is currently working on. Attached is the document from Amy. I have highlighted the main points that I would want to have included in the slides, trying if possible to mirror the same features that are going to be included in the description of the immunomodulator study.

See what you think. I stand ready to look at ppts anytime this evening.

One question about the immunomodulator trial that I noticed in Moncef's note – has FDA agreed with the plan to move straight into phase 3 from a safety and efficacy standpoint?

Thanks, Francis

From: Wholley, David (FNIH) [T] <(b) (6)>
Sent: Friday, May 29, 2020 1:59 PM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gonzalez, Nina <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: Key messages re: immunomodulators for slides for Moncef meeting tomorrow 5/30

Francis:

Here's the outline of the slides I am asking Deloitte to work to put together with key messages. I don't know if you or Ashley have a good version of slide #1, it is more of an OWS slide than an ACTIV one. I also don't know what input NHLBI wants to provide; I took the liberty of naming the anticoag MP as "ACTIV-4" in the interest of teaming up on a

commonly branded strategy, hope that is OK. I am providing this to Deloitte now so they can get going on starting the slides, but please feel free to highlight maybe in red any wording you want changed or additions you would add in the meantime, and copy all on the reply.

- Maybe a diagram slide just reminding Moncef that OWS/Therapeutics and ACTIV are working together
- OWS/ACTIV Therapeutics has been taking a **portfolio** approach to addressing the dramatic health and economic challenges posed by the pandemic, with harmonized efforts that address both disease etiology and symptomology.
 - ACTIV Baricitinib (ACTT2, sponsored by NIAID) – in progress
 - ACTIV hiVIG (sponsored by NIAID) - in progress
 - ACTIV-1 – Inpatient Master Protocol of 3 host-targeted immune modulators (using CRO) – (Phase III) – ready to launch late June
 - ACTIV-2* – Neutralizing Monoclonal Antibodies Outpatient Master Protocol (using NIAID ACTG Network + CRO) – (Phase II/III) – projected launch June
 - ACTIV-3* – Neutralizing Monoclonal Antibodies Inpatient Master Protocol (NIAID INSIGHT Network + NHLBI PETAL Network + CRO) – (Phase II/III) – projected launch July
 - ACTIV-4 – Inpatient Master Protocols of 3+ Anticoagulant Therapies, and eventually, Anticoagulant+Immune Modulator Combinations (NHLBI-NINDS “Master” Network) – (Phase II/III) – projected launch late June
 - ACTIV-5 – De Novo Master Protocol Structure to test promising agents not effectively evaluated elsewhere (e.g., antivirals) – similar design to the mAb protocols, networks/sites/agents in discussions now – projected launch August (*if needed; i.e. if agents are not incorporated into mAb protocols*)
 - * current priority
 - [for this slide I think you can use the Agent Prioritization Snapshot slide (#12) from May 20 ACTIV EC call as a base
- Prioritization Process (v 2.0) for ACTIV : (slide 14 from May 20 EC deck)
- Results of First Agent Prioritization Reviews (slide 13 from May 20 deck)
 - [Key Criteria for Scoring (slide 15 from 5/20) can go to backup
- Prioritization and Protocol Design: Who is Involved – two-box slide containing names and affiliations of those involved in the Prioritization and MP Subgroups (quality folks!)
- ACTIV-1 Protocol for immunomodulators
 - Agent prioritization included input from COVID R&D Leadership Consortium planned testing of 8-9 repurposed agents funded by industry (2 highest priority agents switched to ACTIV-1)
 - 3 agents chosen are well-established anti-inflammatories with solid rationale for MOA in COVID-19, not already being adequately tested elsewhere
 - All 3 either have initial Phase II data or are currently running company-sponsored Phase II trials = high POS
 - Phase III master protocol design for ACTIV-1 includes aggressive efficacy and futility assessments to allow for early stopping at 25%, 50%, and 75% accrual, in order to quickly drop agents not showing efficacy (like a Phase II/III progression design, but design was faster for quicker launch)
 - Companies have agreed to share data + common control arm+ common endpoints + DSMB = efficiency and ability to compare results across arms (this does not happen if companies test separately)
 - Protocol is 80% complete
 - Substantial input from 25+ industry, academic, and government experts, including FDA clinical and stats
 - Statisticians include some of the best in the world for master protocol design: Lisa LaVange (UNC), Karen Price (Lilly), Michael Proschan (NIAID), Sandeep Menon (Pfizer)
 - All three companies have written their sections of the protocols, which are being merged into the master design
 - Working with OWS/BARDA on choice of CRO to run the trial; (b) (5)
- “ACTIV-4” Protocol for anticoagulants

- Need bullets from NHBLI on this. Should emphasize similar themes (robust choice of agents through ACTIV process, powered by NHLBI/NINDS “network of networks” with rapid contracting and startup practices, protocol being drafted in parallel (ACTIV WG review), inclusion of vital natural history disease/treatment data, cost and justification, etc.)
- Maybe a final slide summarizing the budget asks? Should it include preclinical or just the clinical stuff? And perhaps NIH (Ashley) should draft that one given the sensitivity around the numbers?

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/15/2020 7:21:22 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collis]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner [(b) (6) Kerth Gottesdiener [(b) (6) Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Elliott Levy [(b) (6) Sandeep Menon [(b) (6) Amanda Peppercorn [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn [(b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Vincent, Michael [(b) (6) Wung, Peter /US [(b) (6) Karen Lynn Price [(b) (6)]; Pamela Tenaerts, M.D. [(b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy [(b) (6) Beumont-Mauviel, Maria [JRDUS] [(b) (6) i com]; Peeters, Monika [JRDBE] [(b) (6) Woodfall, Brian [JRDUS] [(b) (6) Van Heeswijk, Rolf [JRDBE] [(b) (6)]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Bharucha_David [(b) (6) Gavin, Brian [(b) (6) Sadeh, Jonathan [(b) (6) Harler, Mary Beth [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Mary Biggs [(b) (6) Demarcus [(b) (6) Macone, Erin [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [(b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melsheimer, Rich [CNTNL] [(b) (6)]

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #20

Attachments: ACTIV Therapeutics Clinical Master Protocol Sub Group 22May2020 Meeting Guide.pdf; Agenda capture 1.PNG
Location: <https://fnih.zoom>. (b) (6)

Start: 5/22/2020 6:00:00 PM
End: 5/22/2020 6:30:00 PM
Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Caro, R. Angelo (FDA/CDER); Mark E sner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER), Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson Amy (NIH/NHLBI) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Brown, Jeremy (NIH/NINDS) [E]; Bharucha David; Gavin, Brian; Sadeh, Jonathan; Harler, Mary Beth

Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Melsheimer, Rich [CNTNL]

Dear ACTIV TX-Clinical Master Protocol Subgroup,

For this meeting today, we have decide to split this meeting into two meetings to make most efficient use of everyone's time. This first 30 minute meeting will be the entire group with the companies for ACTIV-1 to discuss the next steps for this protocol. The second 30 minutes will now become a meeting of the mAb Steering Committee to finalize some decisions for the ACTIV-2 protocol that need to be completed by EOD today.

Thanks for your understanding.

Please find attached the slides for this first meeting today.

Thanks, Stacey

Join Zoom Meeting
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US (Houston)
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Meeting ID: (b) (6)
Password: (b) (6)
Find your local number: <https://fnih.zoom.us/j> (b) (6)

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/30/2020 4:06:41 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: Fwd: STAT News article: Human Challenge Trials

FYI

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
(b) (6)

From: Gorman, Greta (FNIH) [T] <(b) (6)>
Sent: Friday, May 29, 2020 5:48 PM
To: Myles, Renate (NIH/OD) [E]
Cc: Meltzer, Abbey (FNIH) [T]
Subject: FW: STAT News article: Human Challenge Trials

Hi Renate,

FYI. We are not going to respond to this person. Just keeping you in the loop.

Best,
Greta

From: Santos, Michael (FNIH) [T] <(b) (6)>
Sent: Friday, May 29, 2020 4:14 PM
To: Gorman, Greta (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Freire Maria (FNIH) [T] <(b) (6)>
Cc: Meltzer, Abbey (FNIH) [T] <(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)>
Subject: FW: STAT News article: Human Challenge Trials

Hi Greta, David, Maria,

An email was sent from someone at the main pro-human challenge model study organization to the entire Vaccines Working Group and a bunch more people (you can see the long To and CC lists below). Someone clearly leaked an email to them that they pulled the addresses from. It's not immediately clear whether our draft manuscript was also leaked to them, but I think we can assume that it was. I have not circulated the submitted manuscript to the WG yet because I was worried about it being leaked ahead of publication.

There's nothing especially problematic with the email below or with the STAT article. They are more optimistic on timeline than we are, and more comfortable with exposing people to unknown risks, but in a reasonably argued way.

My default action here is no response of any kind. But of course I would appreciate your advice on what, if anything, we should do.

(Related: I have asked our manuscript writing team to update us as soon as they hear back from NEJM. No word yet.)

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Sophie Rose <(b) (6)>
Sent: Friday, May 29, 2020 3:30 PM
To: Santos, Michael (FNIH) [T] <(b) (6)> Arvin, Ann <(b) (6)> paula <(b) (6)>
(b) (6) (b) (6) (b) (6) (b) (6) Lowy, Douglas (NIH/NCI)
[E] <(b) (6)> (b) (6) Haynes, Barton <(b) (6)>
(b) (6) ; Beth Bell (b) (6)
(b) (6) Marks, Peter (FDA/CBER) <(b) (6)> Mascola, John (NIH/VRC) [E]
<(b) (6)> (b) (6) Nelson L CIV USARMY MEDCOM WRAIR (USA)
<(b) (6)> Messonnier, Nancy (CDC/DDID/NCIRD/OD) <(b) (6)> Offit, Paul
<(b) (6)> Seals, Jonathan (OS/ASPR/BARDA) <(b) (6)> (b) (6) Tal
Zaks <(b) (6)>
Cc: Brett <(b) (6)> Austin, Sarah (NIH/NIAID) [E] <(b) (6)> (b) (6)
(b) (6) (b) (6) Isabel Ramsey <(b) (6)> Johnson,
Maureen (NIH/NCI) [E] <(b) (6)> Kozlowski, Mary (NIH/NCI) [C] <(b) (6)>
(b) (6) (b) (6) (b) (6) (b) (6)
(b) (6) Cohen, Myron <myron> (b) (6) Macaya [JRDUS] <(b) (6)>
Erbelding, Emily (NIH/NIAID) [E] <(b) (6)> Peter B <(b) (6)> Paul Gillard
<(b) (6)> (b) (6) Gruber, Marion (FDA/CBER) <(b) (6)> Sanjay
/US <(b) (6)> Hamilton, Hollie (OS/ASPR/BARDA) <(b) (6)>
(b) (6) Ledgerwood, Julie (NIH/NIAID) [E] <(b) (6)> Maarten [JRDNL]
<(b) (6)> Marovich, Mary (NIH/NIAID) [E] <(b) (6)> Kathleen Neuzil
<(b) (6)> Robb, Merlin <(b) (6)> (b) (6) Michael Watson (x)
<(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)> Qashu, Felicia (NIH/OD) [E]
<(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)>
(b) (6) Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> (b) (6) Menetski,
Joseph (FNIH) [T] <(b) (6)> Rosa Maria <(b) (6)> Adam, Stacey (FNIH) [T]
<(b) (6)> Elizabeth <(b) (6)> Tountas, Karen (FNIH) [T] <(b) (6)> Jonathan
<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Gonzalez, Nina
<(b) (6)> Benjamin <(b) (6)>
Subject: STAT News article: Human Challenge Trials

Dear Dr. Santos,

I thought your colleagues on the ACTIV Vaccine Working Group might be interested in this STAT News article that was published yesterday by my co-founder, Josh Morrison, entitled "Challenge trials can speed development of a Covid-19 vaccine. Planning for them needs to start now."

<https://www.statnews.com/2020/05/28/challenge-trials-speed-development-covid-19-vaccine-start-planning-now/>

As of May 29, 2020, 26,000+ volunteers from over 100 countries have signed up to participate in human challenge studies to advance the development of a safe and effective SARS-CoV-2 vaccine. While we agree that the utility of challenge trials is not a foregone conclusion, there is no

question that they have enormous potential value. As such, all of us at 1Day Sooner believe that planning for challenge trials should start now.

We have identified a number of funders interested in supporting the viral GMP phase of challenge trial preparations—and if anyone is aware of potential manufacturers for this endeavor (now that Ology has been awarded a Department of Defense contract and thus does not have capacity), we would appreciate any connections you may be able to facilitate.

Kind Regards,
Sophie
Co-Founder at 1Day Sooner

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 7/16/2020 2:46:35 PM
To: Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesd ener, Keith | (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Eliot | (b) (6) Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6) Garner, Carl | (b) (6) Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Timothy Burgess [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner | (b) (6) Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative

Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Philips, L Revell CIV DTRA RD (USA) | (b) (6) Petrowick, Martha - 0449 - MITLL | (b) (6)

(b) (6)
CC: Bethany Stokes | (b) (6) Colvis, Christine (NIH/NCATS) [E]
[//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy
| (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E]
[//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
[//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n], Young, John
(b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6)
Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T]
[//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Salathin, Carla
| (b) (6)]; Tountas, Karen (FNIH) [T] [//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
[//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
[T] [//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
(b) (6) Tolman, Brett | (b) (6)]; Alvarez, Rosa | (b) (6)
Gonzalez, Nina [//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio | (b) (6) Rose
Li Central Account | (b) (6) Anderson, Margaret | (b) (6) Lucas
Smaldon | (b) (6) Stratton, Benjamin | (b) (6)
(b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E]
[//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
(NIH/NHLBI) [E] [//o=ExchangeLabs/ou=Exchange Administrative Group
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(FDA/CDER) [//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q.
| (b) (6) Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
[//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei
(NIH/NHLBI) [E] [//o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) | (b) (6)

Subject: ACTIV Therapeutics-Clinical Working Group Meeting
Attachments: ACTIV TX-Clinical Working Group Meeting Guide 20200716.pdf
Location: <https://fnih.zoom>. (b) (6)

Start: 7/16/2020 5:00:00 PM
End: 7/16/2020 6:00:00 PM
Show Time As: Tentative

Recurrence: Weekly
every Thursday from 1:00 PM to 2:00 PM

Required Attendees: Higgs, Elizabeth (NIH/NIAID) [E]; Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Prosch, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia (FDA/CDER); Amanda Peppercorn; Garner, Carl; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] (b) (6); Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner; Beigel, John (NIH) [E]; Phillips, L. Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL; (b) (6)

Optional Attendees: Bethany Stokes; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel, Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose Li Central Account; Anderson, Margaret; Lucas Smalldon; Stratton, Benjamin; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD) [E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Chen, Helen Q.; Wung, Peter /US; Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Alan (NIH/NHLBI) [E]; Kindzelski, Andrei (NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA)

Dear ACTIV TX-Clinical WG,

Please find attached the slides with the agenda for today's meeting. As requested, we will be receiving an update from the Vaccine's WG as part of the meeting today.

Thanks,
Stacey

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(b) (6)

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/30/2020 1:52:42 AM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Mar a (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Stacey said there is collection of samples for genetic characterization in ACTIV-3 Copying her for clarification

From: Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Sent: Wednesday, July 29, 2020 6:20 PM
To: Wholley, David (FNIH) [T] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)> Anderson, James (NIH/OD) [E] <(b) (6)> Parker, Ashley (NIH/OD) [E] <(b) (6)>
Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

I am not aware of plans to do any genomics in ACTIV-3 as written. My guess it a similar situation for ACTIV-2. One could do amendments to add genomics but I am not advocating that approach given the time/complexity it would add. As noted, we have large observational cohort studies looking at genomics. I think it is something we could ask Team 2 to evaluate in the context of the treatment studies.

Cliff

From: "Wholley, David (FNIH) [T]" <(b) (6)>
Date: Wednesday, July 29, 2020 at 5:58 PM
To: "Collins, Francis (NIH/OD) [E]" <(b) (6)> , "Freire, Maria (FNIH) [T]" <(b) (6)> "Austin, Christopher (NIH/NCATS) [E]" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Lawrence Tabak <(b) (6)>" <(b) (6)> "Anderson, James (NIH/OD) [E]" <(b) (6)> , "Parker, Ashley (NIH/OD) [E]" <(b) (6)>
Subject: RE: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Francis, I composed the following reply to Robert for your consideration. I'm happy to send it (he wrote to both of us) or you can; feel free to edit of course in either case. Cliff, please weigh in on how I have characterized the NIAID study you mentioned this morning. Thanks

Hi Robert:

Point taken. As always, we have to balance the benefits associated with genetic testing vs. the burden on sites of collection and banking and the need to make sure our trials are progressing as rapidly as possible. ACTIV-3 and ACTIV-4 are indeed planning to collect material for genetic testing from a reasonable subset of participants. ACTIV-1 does not have that in plan at this point, but may be willing to consider a substudy at more high functioning sites. This would be a hard sell for ACTIV-2, of course, as it is an outpatient cohort. FYI, NIAID is also planning a fairly large observational study that will include genetic analysis. Please let me know if you have other thoughts.

Regards,
David

From: Collins, Francis (NIH/OD) [E] <(b) (6)>

Sent: Wednesday, July 29, 2020 7:43 AM

To: Freire, Maria (FNIH) [T] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> >; Austin, Christopher (NIH/NCATS) [E] <(b) (6)>, Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Anderson, James (NIH/OD) [E] <(b) (6)> >; Parker, Ashley (NIH/OD) [E] <(b) (6)>

Subject: FW: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

From: Plenge, Robert <(b) (6)>

Sent: Wednesday, July 29, 2020 7:33 AM

To: Wholley, David (FNIH) [T] <(b) (6)> Collins, Francis (NIH/OD) [E] <(b) (6)>

Subject: Re: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Given the recent genetic data ([here](#), [here](#), [here](#), [here](#)), is it worth considering more routine genetic testing (e.g., GWAS, WES) in ACTIV trials to guide future repurposing?

From: "Melencio, Cheryl (FNIH) [T]" <(b) (6)> on behalf of "Wholley, David (FNIH) [T]" <(b) (6)>

Date: Tuesday, July 28, 2020 at 10:55 PM

To: "Austin, Christopher (NIH/NCATS) [E]" <(b) (6)> "Bancel, Stephane" <(b) (6)> "Carter, Kara" <(b) (6)> "Cavaleri, Marco" <(b) (6)> "Cihlar, Tomas" <(b) (6)> "Collins, Francis (NIH/OD) [E]" <(b) (6)> "Corey, Larry" <(b) (6)> "Culp, Michelle (NIH/OD) [E]" <(b) (6)> "Disbrow, Gary (OS/ASPR/BARDA)" <(b) (6)> "Dolsten, Mikae" <(b) (6)> "Erbelding, Emily (NIH/NIAID) [E]" <(b) (6)> "Erck, Stan" <(b) (6)> "Fauci, Anthony (NIH/NIAID) [E]" <(b) (6)> "Freire, Maria (FNIH) [T]" <(b) (6)> "Gadbois, Ellen (NIH/OD) [E]" <(b) (6)> "Gibbons, Gary (NIH/NHLBI) [E]" <(b) (6)> "Hudson, Thomas" <(b) (6)> "James, Stephanie (FNIH) [T]" <(b) (6)> "Johnson, Robert (OS/ASPR/BARDA)" <(b) (6)> "Kramer, Lynn" <(b) (6)> "Lane, Cliff (NIH/NIAID) [E]" <(b) (6)> "Lepore, John" <(b) (6)> "Marks, Peter (FDA/CBER)" <(b) (6)> "Marston, Hilary (NIH/NIAID) [E]" <(b) (6)> "Mascola, John (NIH/VRC) [E]" <(b) (6)> "Meeker, David" <(b) (6)> "Menetski, Joseph (FNIH) [T]" <(b) (6)> "Messonnier, Nancy (CDC/DDID/NCIRD/OD)" <(b) (6)> "Pandya, Hitesh" <(b) (6)> "Pangalos, Mene" <(b) (6)> "Pao, William" <(b) (6)> "Parker, Ashley (NIH/OD) [E]" <(b) (6)> "Paul, Steve" <(b) (6)> "Perlmutter, Roger" <(b) (6)> "Plenge, Robert" <(b) (6)>

(b) (6) "Plump, Andy" < (b) (6) Rachel Ramoni
 , "Rasi, Guido" (b) (6) >, "Reed, John"
 < (b) (6) "Reese, David" < (b) (6) "Rouse, Doris" < (b) (6) "Santos,
 Michael (FNIH) [T]" < (b) (6) "Skovronsky, Daniel" (b) (6) "Stein, Peter
 (FDA/CDER)" (b) (6) "Stoffels, Paul" < (b) (6) "Tabak, Lawrence (NIH/OD)
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 "Wholley, David (FNIH) [T]" (b) (6) "Woodcock, Janet (FDA/CDER)"
 < (b) (6) "Young, John" < (b) (6) "Colvis, Christine (NIH/NCATS)
 [E]" (b) (6) "Desrosiers, Betsy" (b) (6) >, Eric Hughes
 < (b) (6) "Jansen, Kathrin" < (b) (6) "Kurilla, Michael (NIH/NCATS)
 [E]" (b) (6) "Lowy, Douglas (NCI)" < (b) (6) "Read, Sarah (NIH/NIAID) [E]"
 (b) (6) "Young, John" (b) (6)
 Cc: "Bianchi, Diana (NIH/NICHD) [E]" < (b) (6) "Byrnes, Noni (NIH/CSR) [E]"
 < (b) (6) "Glass, Roger (NIH/FIC) [E]" < (b) (6) "Hodes, Richard (NIH/NIA) [E]"
 (b) (6) "Koob, George (NIH/NIAAA) [E]" (b) (6) >, "Koroshetz, Walter
 (NIH/NINDS) [E]" < (b) (6) "Langevin, Helene (NIH/NCCIH) [E]"
 (b) (6) "Norris, Andrea (NIH/CIT) [E]" < (b) (6) "Perez-Stable, Eliseo
 (NIH/NIMHD) [E]" (b) (6) "Rodgers, Griffin (NIH/NIDDK) [E]"
 < (b) (6) "Schwetz, Tara (NIH/OD) [E]" < (b) (6) "Sharpless, Norman
 (NIH/NCI) [E]" < (b) (6) "Tucci, Debara (NIH/NIDCD) [E]" < (b) (6)
 "Tumma, Santa (NIH/NEI) [E]" (b) (6) >, "Volkow, Nora (NIH/NIDA) [E]"
 (b) (6) "Woychik, Rick (NIH/NIEHS) [E]" < (b) (6) "Adam, Stacey (FNIH) [T]"
 < (b) (6) "Alvarez, Rosa" (b) (6) "Anderson, Margaret"
 < (b) (6) "Chen, Helen" < (b) (6) "Elsaid, Olivia"
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 < (b) (6) "Menetski, Joseph (FNIH) [T]" < (b) (6) "Santos, Michael (FNIH) [T]"
 < (b) (6) "Stratton, Ben" < (b) (6) "Tolman, Brett" (b) (6) >,
 "Tountas, Karen (FNIH) [T]" < (b) (6) "Wachtel, Jonathan" < (b) (6) "Wholley,
 David (FNIH) [T]" < (b) (6) "Anderson, James (NIH/OD) [E]" < (b) (6)
 "Burklow, John (NIH/OD) [E]" < (b) (6) "Castillejos, Carlos" < (b) (6) "Culp,
 Michelle (NIH/OD) [E]" < (b) (6) FNIH Central Account < (b) (6) "Freire,
 Maria (FNIH) [T]" (b) (6) "Gadbois, Ellen (NIH/OD) [E]" (b) (6) "Wolinetz,
 Carrie (NIH/OD) [E]" < (b) (6) "Burklow, John (NIH/OD) [E]" (b) (6)
 "Gorman, Greta (FNIH) [T]" (b) (6) >, "Hallett, Adrienne (NIH/OD) [E]"
 (b) (6) "Meltzer, Abbey (FNIH) [T]" (b) (6) "Myles, Renate (NIH/OD) [E]"
 < (b) (6) "Melencio, Cheryl (FNIH) [T]" < (b) (6)

Subject: [EXTERNAL] Materials for July 29 ACTIV Executive Committee Teleconference

Resent-From: < (b) (6) >

[Use CAUTION when opening links/attachments]

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 2:30 PM to 4:00 PM Eastern U.S. time tomorrow, Wednesday July 29. I have also attached notes from our July 1 Leadership Team meeting as well as our last ACTIV EC meeting on July 15.

The Zoom meeting information is:

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(b) (6)

Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
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fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

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Sent: 5/13/2020 1:57:04 AM
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CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Agenda for ACTIV EC meeting tomorrow morning at 8:00 AM Eastern US Time
Attachments: Agenda ACTIV EC Meeting #1 5-13-20.docx; Proposal for ACTIV leadership vF 051220.pdf

Dear ACTIV EC members, Working Group Co-Chairs, and meeting participants:
Please see attached the agenda for our meeting tomorrow morning (via Zoom) and a copy of the letter from the Therapeutics- Clinical Working Group you received earlier today, for our discussion.

Please let Joe Menetski or Cheryl Melencio know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNHI earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Collins, Francis (NIH/OD) [E] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]

Sent: 10/16/2020 9:45:36 PM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]; Chang, Soju (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99b3263e72a94bfa9ded3f82c4dae59c-changsoju]; (b) (6) [(b) (6) 'Gavin, Brian' | (b) (6) 'Sadeh, Jonathan' | (b) (6) 'Melsheimer, Rich [CNTNL]' | (b) (6) 'Beumont-Mauviel, Maria [JRDUS]' | (b) (6) 'Bharucha_David' | (b) (6) 'Ferguson_William' | (b) (6) Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; 'LaVange, Lisa M' | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Gardner, Bobbi (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3dd21d20185e4e46a20a6eb89c314580-gardnerbw]; 'Sandeep Menon' | (b) (6) 'Yong, Florence H' | (b) (6) 'Trank, Christina' | (b) (6) 'Moyo, Vusi' | (b) (6) 'Kimmel, Bridget [JRDUS]' | (b) (6) Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Marti, Emily (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=970fb6ea63944699aa433fb034a0f63f-carlsonel]; Eisnor, Derek (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae393740634d4ec9954494c0c2ef669a-Derek.Eisno]; (b) (6) (b) (6) Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebcf48879f92169bd7644e29-Janet.Woodc]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; 'Montgomery, Stephanie' | (b) (6) O'Sullivan_Alexandra | (b) (6) Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]; Neta Nelson [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d10b8fd5dff411eb1d6f8f4892e27e3-nnelson.tec]; Butler, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4782eaa72024479197826e3d71d5584c-sbutler.tec]; Danie Benjamin Jr, M.D., Ph.D. | (b) (6) Theresa Jason | (b) (6) Molina, Daniel | (b) (6) Rose Beci | (b) (6) Lind, Brian (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=486ebcc6ebe34d08a691e66632ed5005-lindbj]; Mason, Robin (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77156b112de94c439dbccb6894954618-Robin.Mason]; O'rourke, Anna (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a43de8d7c474c538615405753ccfb6c-Anna.O_rour]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lori Hudson, Ph.D. | (b) (6) "Huyen Cao" < (b) (6) ["Huyen Cao" < (b) (6) Huyen Cao | (b) (6) Brody, Betty (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecad8c87c49d4f018bd2530beaf4a30d-Betty.Brody]; Chiang, Anna

(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=aa42127fa32b4d0fa0ccce5799cf419f-Anna.Chiang]; Schmidt, Jeffrey
(OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3431da5ab88f4204858d4c6fe19aaa7a-Jeffrey Sch]

Subject: RE: 1st ACTIV-1 patient has been randomized

Terrific! I just talked about the study with Wolf Blitzer on CNN – it's great to have it underway.

Many thanks to all who worked so hard to get to this point. Onward!

Francis

From: Bozzette, Sam (NIH/NCATS) [E] <(b) (6)>
Sent: Friday, October 16, 2020 4:48 PM
To: Boucher, Cynthia (NIH/NCATS) [E] <(b) (6)> Atkinson, Jane (NIH/NCATS) [E]
<(b) (6)> Chang, Soju (NIH/NCATS) [E] <(b) (6)> 'Sadeh, Jonathan' <(b) (6)>
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Cc: 'Montgomery, Stephanie' <(b) (6)> O'Sullivan_Alexandra
<(b) (6)> Stock, Thomas (HHS/IOS) <(b) (6)> Neta Nelson
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Rose Beci <(b) (6)> Lind, Brian (NIH/NCATS) [E] <(b) (6)> Mason, Robin (OS/ASPR/BARDA)
<(b) (6)> O'rourke, Anna (OS/ASPR/BARDA) (CTR) <Anna. (b) (6)> Austin, Christopher
(NIH/NCATS) [E] <(b) (6)> Lori Hudson, Ph.D. <(b) (6)> "Huyen Cao"
<(b) (6)> <"Huyen Cao" <(b) (6)> Huyen Cao <(b) (6)> Brody, Betty
(OS/ASPR/BARDA) <(b) (6)> Chiang, Anna (OS/ASPR/BARDA) <(b) (6)> Schmidt, Jeffrey
(OS/ASPR/BARDA) <(b) (6)>
Subject: 1st ACTIV-1 patient has been randomized

Hello:

The first patient has been randomized into ACTIV-1. Congratulations to all, especially Bill Powderly, Jane O'Halloran, and the rest of the Wash U team.

Happy weekend to all!
Sam B

Sam Bozzette, MD, PhD
Chief Medical Officer
Immediate Office of the Director

*National Center for Advancing Translational Sciences
National Institutes of Health*

6701 Democracy Blvd., Room 926

Bethesda, MD 20892

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NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.

GADB0000001379-2517563

(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Desrosiers, Betsy [E] [mailto:bdesrosiers@exchange.nih.gov]; Eric Hughes [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes], Jansen, Kathrin [E] [mailto:kjansen@exchange.nih.gov]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Adam, Stacey (FNIH) [T] [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson [E] [mailto:marganderson@exchange.nih.gov]; Appell, Evan [E] [mailto:evanappell@exchange.nih.gov]; Chen, Helen [E] [mailto:hchen@exchange.nih.gov]; Connelly, Sarah [E] [mailto:sconnelly@exchange.nih.gov]; Gonzalez, Nina [E] [mailto:nngonzalez@exchange.nih.gov]; Hawk, Harrison [E] [mailto:hhawk@exchange.nih.gov]; Mendelson, Jesse [E] [mailto:jmendon@exchange.nih.gov]; Nasr, Hana [E] [mailto:hana.nasr@exchange.nih.gov]; Sorosa, Alex [E] [mailto:alex.sorosa@exchange.nih.gov]; Stratton, Benjamin [E] [mailto:bstratton@exchange.nih.gov]; btolman [E] [mailto:btolman@exchange.nih.gov]; Wachtel, Jonathan [E] [mailto:jwachtel@exchange.nih.gov]; Anderson, James (NIH/OD) [E] [mailto:janderson@exchange.nih.gov]; Burklow, John (NIH/OD) [E] [mailto:jburklow@exchange.nih.gov]; Carluccio, Dana [E] [mailto:dcarluccio@exchange.nih.gov]; Castilejos, Carlos [E] [mailto:ccastilejos@exchange.nih.gov]; FNIH Central Account [E] [mailto:central@exchange.nih.gov]; Hallett, Adrienne (NIH/OD) [E] [mailto:ahallett@exchange.nih.gov]; Lumsden, Joanne (NIH/NCATS) [C] [mailto:jlumsden@exchange.nih.gov]; Myles, Renate (NIH/OD) [E] [mailto:rmyles@exchange.nih.gov]; Wolnetz, Carrie (NIH/OD) [E] [mailto:cwolnetz@exchange.nih.gov]; Meltzer, Abbey (FNIH) [T] [E] [mailto:ameltzer@exchange.nih.gov]; Austin, Sarah (NIH/NIAID) [E] [mailto:saustrin@exchange.nih.gov]; Barasch, Kimberly (NIH/NIAID) [C] [mailto:kbarasch@exchange.nih.gov]; Bell, Julie [E] [mailto:jbell@exchange.nih.gov]; Burrus-Shaw, Cyndi (NIH/OD) [E] [mailto:cburrus@exchange.nih.gov]; Carver, Trea (NIH) [C] [mailto:tcarver@exchange.nih.gov]; Caulfield, Anita [E] [mailto:anita.caulfield@exchange.nih.gov]; Coan, Amanda [E] [mailto:acoan@exchange.nih.gov]; Conrad, Patricia (NIH/NIAID) [E] [mailto:pconrad@exchange.nih.gov]; Dimishkov, Roxanne (NIH/NHLBI) [C] [mailto:rdimishkov@exchange.nih.gov]; Edl, Susan [E] [mailto:sedl@exchange.nih.gov]; Fuhrer, Nicole [E] [mailto:nfuhrer@exchange.nih.gov]; Giorgi, Sara [E] [mailto:sgiorgi@exchange.nih.gov]; Hoban, Michele [E] [mailto:mhoban@exchange.nih.gov]; Hoffstetter, Renata (FNIH) [T] [E] [mailto:renata.hoffstetter@exchange.nih.gov];

CC:

Iberdemaj, Vaide | (b) (6) Jenkins, Christine S. | (b) (6) m], Krack, Kimberly [kimberly]; (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Lever, Susan | (b) (6) Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]; Martin, Melisa | (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth | (b) (6) Perala, Mie | (b) (6) Protasiewicz, Ann | (b) (6) Riccobene, Kim | (b) (6) Riffin, Mary | (b) (6) Ripley, Nadege | (b) (6) Schuster, Donna | (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fbb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Togash, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togashm]; Underwood, Nancy | (b) (6)]; Zottoli, Jessica | (b) (6)]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugneskp]; Magbie-Robinson, Kim (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74a5b9cea10b4f919d9db20c8aaec3e7-magbierobin]

Subject: ACTIV Leadership Team Call #16

Location: <https://nih.zoom.us> (b) (6)

Start: 5/28/2021 1:00:00 PM

End: 5/28/2021 2:30:00 PM

Show Time As: Tentative

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Davey, Victoria; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauci, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Virgin, Skip; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathryn; Kurla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Nasr, Hana; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Wachter, Jonathan; Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Lumsden, Joanne (NIH/NCATS) [C]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]

Optional Attendees: Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfield, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorgi, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; Magbie-Robinson, Kim (NIH/OD) [C]; Martin, Melisa; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim;

From: Koroshetz, Walter (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8338DD7CDCD432E986961F1548C5EC6-KOROSHETZW]
Sent: 5/4/2020 1:21:51 AM
To: Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adams4]; Eric Hughes (b) (6) Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli (b) (6) Naimish Patel (b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John (b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike (b) (6) Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael (b) (6) Keith Gottesdiener (b) (6) Elliott Levy (b) (6) Wung, Peter /US (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner (b) (6)
CC: Elizabeth Kim (b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Sarath n, Carla (b) (6); Merritt, Gabriella Marie (b) (6) Romanowski, Jake (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon (b) (6) m]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Thanks very much John. Had a stupid question.

The drug was obviously built for HIV which requires activity throughout the body. Has anyone considered whether for COVID-19 a nebulized administration down the trachea into the lung would enable more potent effects given that is the site of first viral entry? Maybe enable higher doses without untoward effects.

Reason to consider checking this for other anti-virals given in early stages of the illness?

Walter

From: Mellors, John W (b) (6)
Sent: Sunday, May 3, 2020 4:05 PM
To: Adam, Stacey (FNIH) [T] <(b) (6)> Eric Hughes <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Ruxandra Draghia-Akli <(b) (6)> Naimish Patel <(b) (6)> Colvis, Christine (NIH/NCATS) [E] <(b) (6)> Young, John <(b) (6)> Stein, Peter (FDA/CDER) <(b) (6)> Poole, Mike <(b) (6)> Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)> Vincent, Michael <(b) (6)> Keith Gottesdiener <(b) (6)> Elliott Levy <(b) (6)> Wung, Peter /US <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Higgs, Elizabeth (NIH/NIAID) [E] <(b) (6)> Carlos O Garner <garner (b) (6)>

Cc: Elizabeth Kim <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Salathin, Carla
<(b) (6)> Merritt, Gabriella Marie <(b) (6)> Romanowski, Jake <(b) (6)>
Parker, Ashley (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl
(FNIH) [T] <(b) (6)> Lucas Smalldon <(b) (6)> Walker, Paula (NIH/NINDS)
[E] <(b) (6)> Ward, Jackie (NIH/NINDS) [E] <(b) (6)>
Subject: RE: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Useful EMA review of remdesivir. Substrate and weak inhibitor of CYP3A. Not clear what the effect of 3A4 inhibitor would be of complex metabolism

From: Adam, Stacey (FNIH) [T] [mailto:(b) (6)]

Sent: Sunday, May 3, 2020 2:31 PM

To: Eric Hughes <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)> Ruxandra Draghia-
Akli <(b) (6)> Mellors, John W <(b) (6)> Naimish Patel <(b) (6)> Colvis,
Christine (NIH/NCATS) [E] <(b) (6)> Young, John <(b) (6)> Stein, Peter
(FDA/CDER) <(b) (6)> Poole, Mike <(b) (6)> Buchman, Tim
(OS/ASPR/BARDA) (CTR) <(b) (6)> Vincent, Michael <(b) (6)> Keith
Gottesdiener <(b) (6)> Elliott Levy <(b) (6)> Wung, Peter /US
<(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> Higgs, Elizabeth
(NIH/NIAID) [E] <(b) (6)> Carlos O Garner <(b) (6)>
Cc: Elizabeth Kim <(b) (6)> Menetski, Joseph (FNIH) [T] <(b) (6)> Salathin, Carla
<(b) (6)> Merritt, Gabriella Marie <(b) (6)> Romanowski, Jake <(b) (6)>
Parker, Ashley (NIH/OD) [E] <(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl
(FNIH) [T] <(b) (6)> Lucas Smalldon <(b) (6)> Walker, Paula (NIH/NINDS)
[E] <(b) (6)> Ward, Jackie (NIH/NINDS) [E] <(b) (6)>
Subject: Material for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting

Hi ACTIV TX-Clinical Prioritization Subgroup members,

Please find attached the final tally of scores for the agents that came through triage in Wave 1. We will use this document for our discussions today.

For those who sent me comments, I did not want to over whelm the score sheet with multiple rows of information. However, I have those and I will include them in the final record for posterity for this round. You can also feel free to bring them up during the discussion if helpful to the group.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) Mobile: (b) (6)

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Password: (b) (6)

Find your local number: <https://fnih.zoom.us> (b) (6)

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/30/2020 12:30:52 PM

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan (b) (6)]; Collins, Sylva (FDA/CDER) (b) (6) Judy Currier (b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6) Mark Eisner | (b) (6) Keith Gottesdiener (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M. (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) ; Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Amanda Peppercorn | (b) (6) ; Price, Dionne (FDA/CDER) | (b) (6) Rubin, Daniel B. (FDA/CDER) | (b) (6) Shen, Yuan Li (FDA/CDER) | (b) (6) ; Farley, John (FDA/CDER) (b) (6) ; Goff, David (NIH/NHLBI) [E] | (b) (6) Vincent, Michael | (b) (6) Wung, Peter /US | (b) (6) Karen Lynn Price | (b) (6) Pamela Tenaerts, M.D. | (b) (6) ; Koroshetz, Walter (NIH/NINDS) [E] | (b) (6)]

CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6) Wachtel, Jonathan (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] | (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Dimishkov, Roxanne (NIH/NHLBI) [C] | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E] | (b) (6) ; Patterson, Amy (NIH/NHLBI) [E] | (b) (6) Chertow, Jessica (NIH/NHLBI) [E] (b) (6) Paltoo, Dina (NIH/NLM) [E] | (b) (6) Gibbons, Gary (NIH/NHLBI) [E] | (b) (6)

Subject: ACTIV TX-Clinical Master Protocol Subgroup Meeting #12

Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_4May2020 Meeting Guide.pdf; ACTIV Therapeutics Clinical Master Protocol Sub-Group Meeting 4May2020 Agenda.pdf

Location: <https://fnih.zoom>. (b) (6)

Start: 5/4/2020 5:00:00 PM

End: 5/4/2020 6:00:00 PM

Show Time As: Busy

Required Attendees: Adam, Stacey (FNIH) [T]; Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes; Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Koroshetz, Walter (NIH/NINDS) [E]

Optional Attendees: Mary Biggs, Demarcus, Macone, Erin; Tountas, Karen (FNIH) [T], Wachtel, Jonathan, Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T], Dimishkov, Roxanne (NIH/NHLBI) [C]; Hoots, W. Keith (NIH/NHLBI) [E]; Patterson, Amy (NIH/NHLBI) [E]; Chertow, Jessica (NIH/NHLBI) [E]; Paltoo, Dina (NIH/NLM) [E]; Gibbons, Gary (NIH/NHLBI) [E]

Dear TX-Clinical Master Protocol Subgroup,

Please find attach the materials for today's meeting.

1. Agenda
2. Slides

Thanks,

Stacey

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(b) (6)

Sent: 8/26/2020 1:49:02 AM
Subject: FW: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Attachments: 8.26 ACTIV Leadership Team Meeting 20200825 vFinal.pdf; 2020-07-29 ACTIV Leadership Team Meeting Summary fina .pdf; 2020-08-14 Executive Committee Meeting_Summary vFinal.pdf

From: Melencio, Cheryl (FNIH) [T] <(b) (6)> **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, August 25, 2020 9:47 PM
To: Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Bancel, Stephane
<(b) (6)> Carter, Kara <(b) (6)> Cavaleri, Marco
<(b) (6)> Cihlar, Tomas <(b) (6)> Collins, Francis (NIH/OD) [E]
<(b) (6)> Corey, Larry <(b) (6)> Culp, Michelle (NIH/OD) [E] <(b) (6)>
Disbrow, Gary (OS/ASPR/BARDA) <(b) (6)> Dolsten, Mikael <(b) (6)> Erbeling,
Emily (NIH/NIAID) [E] <(b) (6)> Erck, Stan <(b) (6)> Fauci, Anthony (NIH/NIAID) [E]
<(b) (6)> Freire, Maria (FNIH) [T] <(b) (6)> Gadbois, Ellen (NIH/OD) [E]
<(b) (6)> Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)> Hudson, Thomas
<(b) (6)> James, Stephanie (FNIH) [T] <(b) (6)> Johnson, Robert (OS/ASPR/BARDA)
<(b) (6)> Kramer, Lynn <(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)>
Lepore, John <(b) (6)> Marks, Peter (FDA/CBER) <(b) (6)> Marston, Hilary
(NIH/NIAID) [E] <(b) (6)> Mascola, John (NIH/VRC) [E] <(b) (6)> Meeker, David
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Young, John <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Alvarez, Rosa <(b) (6)> Anderson, Margaret
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Gonzalez, Nina <(b) (6)> Hawk, Harrison <(b) (6)> Menetski, Joseph (FNIH) [T]
<(b) (6)> Santos, Michael (FNIH) [T] <(b) (6)> Stratton, Benjamin <(b) (6)>
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<(b) (6)> Wholley, David (FNIH) [T] <(b) (6)> Anderson, James (NIH/OD) [E]
<(b) (6)> Austin, Christopher (NIH/NCATS) [E] <(b) (6)> Burcklow, John (NIH/OD) [E]
<(b) (6)> Castillejos, Carlos <(b) (6)> Culp, Michelle (NIH/OD) [E]
<(b) (6)> FNIH Central Account <(b) (6)> Freire, Maria (FNIH) [T]
<(b) (6)> Gadbois, Ellen (NIH/OD) [E] <(b) (6)> Hallett, Adrienne (NIH/OD) [E]
<(b) (6)> Lane, Cliff (NIH/NIAID) [E] <(b) (6)> Myles, Renate (NIH/OD) [E]
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<(b) (6)> Wolinetz, Carrie (NIH/OD) [E] <(b) (6)> Burcklow, John (NIH/OD) [E]

< (b) (6) Gorman, Greta (FNIH) [T] < (b) (6) . Hallett, Adrienne (NIH/OD) [E]
< (b) (6) Meltzer, Abbey (FNIH) [T] < (b) (6) Myles, Renate (NIH/OD) [E]
< (b) (6) Wolinetz, Carrie (NIH/OD) [E] < (b) (6) Lucas Smalldon
< (b) (6) Villafana, Tonya < (b) (6) Brian Rosen
< (b) (6)

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Importance: High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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Sent: 5/7/2020 8:53:35 PM

To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [(b) (6) Butterson, Joan (b) (6)]; Collins, Sylva (FDA/CDER) [(b) (6) Judy Currier (b) (6)]; De Claro, R. Angelo (FDA/CDER) [(b) (6) Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M. (b) (6) Elliott Levy [(b) (6) Sandeep Menon | (b) (6) ; Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Amanda Peppercorn | (b) (6) ; Price, Dionne (FDA/CDER) | (b) (6) Rubin, Daniel B. (FDA/CDER) | (b) (6) Shen, Yuan Li (FDA/CDER) | (b) (6) ; Farley, John (FDA/CDER) (b) (6) ; Goff, David (NIH/NHLBI) [E] | (b) (6) Vincent, Michael | (b) (6) Wung, Peter /US | (b) (6) Karen Lynn Price | (b) (6) Pamela Tenaerts, M.D. | (b) (6) ; Patterson, Amy (NIH/NHLBI) [E] | (b) (6) ; Smith, David | (b) (6) Kim, Peter (NIH/NIAID) [E] | (b) (6) (b) (6) Eron, Joe (b) (6) Higgs, Elizabeth (NIH/NIAID) [E] | (b) (6) Burgess, Timothy | (b) (6) Beumont-Mauviel, Maria [JRDUS] | (b) (6) Peeters, Monika [JRDBE] | (b) (6) Woodfall, Brian [JRDUS] | (b) (6) Van Heeswijk, Rolf [JRDBE] | (b) (6) ; Mellors, John W (b) (6)

CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6) Wachtel, Jonathan (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] | (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Eron, Joseph J Jr (b) (6) Javan, Arzhang (NIH/NIAID) [E] | (b) (6)]

Subject: ACTIV TX-Clinical Master Protocol Subgroup #15

Attachments: ACTIV Therapeutics-Clinical_MP Subgroup_11May2020 Meeting Guide.pdf; Adapt Out COVID Overview051120.pdf

Location: <https://fnih.zoom.us> (b) (6)

Start: 5/11/2020 5:00:00 PM

End: 5/11/2020 6:30:00 PM

Show Time As: Busy

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Joan Butterson; Collins, Sylva (FDA/CDER); Judy Currier; De Claro, R. Angelo (FDA/CDER); Mark Eisner; Keith Gottesdiener; Eric Hughes, Lisa LaVange; Elliott Levy; Sandeep Menon; Amanda Peppercorn; Proschan, Michael (NIH/NIAID) [E]; Read, Sarah (NIH/NIAID) [E]; Amanda Peppercorn; Price, Dionne (FDA/CDER); Rubin, Daniel B. (FDA/CDER); Shen, Yuan Li (FDA/CDER); Farley, John (FDA/CDER); Goff, David (NIH/NHLBI) [E]; Vincent, Michael; Wung, Peter /US; Karen Lynn Price; Pamela Tenaerts, M.D.; Patterson, Amy (NIH/NHLBI) [E]; Smith, David; Kim, Peter (NIH/NIAID) [E], (b) (6) Eron, Joe, Higgs, Elizabeth (NIH/NIAID) [E]; Burgess, Timothy; Beumont-Mauviel, Maria [JRDUS]; Peeters, Monika [JRDBE]; Woodfall, Brian [JRDUS]; Van Heeswijk, Rolf [JRDBE]; Mellors, John W

Optional Attendees: Mary Biggs, Demarcus; Macone, Erin; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Elizabeth Kim; Parker, Ashley (NIH/OD) [E]; Butcher, Tina; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Eron, Joseph J Jr; Javan, Arzhang (NIH/NIAID) [E]

Dear TX-Clinical Master Protocol Subgroup,

Please find attached the materials for today's call. We will be discussing the statistical simulations the group has put together for ACTT-3, as well as we will have a presentation from the ACTG group on their outpatient master protocol.

Thanks,
Stacey

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From: Tountas Karen (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]

Sent: 5/18/2020 12:22:03 AM

To: Bascles, Lionel [(b) (6) Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron-cohen]; Corey, Larry [(b) (6) Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; Desrosiers, Betsy [(b) (6) Dickens, Jim (NIH/NCATS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12591c90404e46caba73079cf4a5e2ea-dickensj]; Doroshov, James (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1d0fb9f055940c39b387cae2485faa6-doroshovj]; Garner, Carlos [(b) (6) Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Mensah, George (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=284d85649e634a0a91bb0b9aac84846c-mensahga]; Nayak, Seema (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51d5ee6848004578b5bf9c808eca8f6f-nayaksu]; Payton, Manizhe (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81d1c1824bfa438a94da81520a8bca90-paytonma]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Resnansky, Laura [resnansky (b) (6) Sizemore, Christine (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Srinivasan, Badhri [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Vincent, Mike [(b) (6) Wachtel, Jonathan (b) (6)]; Weinmann, Gail (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f38a543b4021483ba67e42af1165dcad-weinmang]

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Hughes, Eric [(b) (6) Jansen, Kathrin [(b) (6) Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Saran (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John [(b) (6) Criffield, Robin [(b) (6) Hamilton, Nancy [(b) (6)]; Me encio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Minnich, Beth [(b) (6) Mueller-Reichenstein, Petra [(b) (6) Pico, Dianna (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=471cb6a63c8846a69073e1e968f3964c-p-codf]; Quadros, Nora [(b) (6) Katz, Rebecca (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e2b174d9bf748e9aa5ed901b4c5a3d9-katzrd]; Hill, Zoe (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a19ee51dca2a443d883a15e025d6e1e0-hillzs]; Adams, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Anderson, Margaret [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Carluccio, Dana [(b) (6) Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencio]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Heaton, Penny [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Li, Rose [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative

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Subject: Summary and action items - CT Capacity WG meeting #8

Attachments: Clinical Trial Capacity Working_Group Meeting 9 Final.pdf

Dear Clinical Trial Capacity Working Group Members,

Attached is the summary and action items for meeting #9 (May 15, 2020) of the full working group. The next full working group meeting is scheduled for Tuesday, May 19 at 9 am eastern time USA.

Cheers!

Karen

Karen H. Toumtas, PhD

Scientific Program Manager

Foundation for the National Institutes of Health

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Sent: 4/30/2020 12:54:05 PM
To: Eric Hughes [(b) (6)]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Ruxandra Draghia-Akli [(b) (6)]; Mellors, John W [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Naimish Patel [(b) (6)]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Young, John [(b) (6)]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Poole, Mike [(b) (6)]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Vincent, Michael [(b) (6)]; Keith Gottesdiener [(b) (6)]; Elliott Levy [(b) (6)]; Wung, Peter /US [(b) (6)]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Carlos O Garner [(b) (6)]
CC: Elizabeth Kim [(b) (6)]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Alvarez, Rosa Maria [(b) (6)]; Salathin, Carla [(b) (6)]; (b) (6) (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Lucas Smalldon [(b) (6)]; Walker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Ward, Jackie (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4114c7d13389454f89fe3411cb3a834f-wardjam]
Subject: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Location: <https://fnih.zoom.us> (b) (6)
Start: 5/5/2020 5:00:00 PM
End: 5/5/2020 6:00:00 PM
Show Time As: Tentative

Required Attendees: Eric Hughes, Read, Sarah (NIH/NIAID) [E]; Ruxandra Draghia-Akli; John Mellors; Naimish Patel; Colvis, Christine (NIH/NCATS) [E]; Young, John; Stein, Peter (FDA/CDER); Poole, Mike; Buchman, Tim (OS/ASPR/BARDA) (CTR); Vincent, Michael; Keith Gottesdiener; Elliott Levy; Wung, Peter /US; Koroshetz, Walter (NIH/NINDS) [E]; Higgs, Elizabeth (NIH/NIAID) [E]; Carlos O Garner
Optional Attendees: Elizabeth Kim; Menetski, Joseph (FNIH) [T]; Alvarez, Rosa Maria; Salathin, Carla; (b) (6) (b) (6)
Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Lucas Smalldon; Walker, Paula (NIH/NINDS) [E]; Ward, Jackie (NIH/OD) [E] (b) (6)

Stacey Adam is inviting you to a scheduled Zoom meeting.

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Sent: 9/24/2020 3:04:25 AM
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CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]
Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Attachments: 8.26 ACTIV Leadership Team Meeting 20200825 vFinal.pdf

Thank you, Francis.

Good morning Patrice,

I've made a few adjustments to the email to go out to the ICD ONLY list this morning – please see below.

Thanks,
Ashley

To: ICD-ONLY-L@LIST.NIH.GOV
Cc: Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>
Bcc: Parker, Ashley (NIH/OD) [E] <(b) (6)>

Dear Colleagues,

As discussed during our conference call yesterday, ICDs (**principals only please; no surrogates or additional staff**) are invited to join the virtual ACTIV leadership team meeting **today August 26, 3:00-4:00pm**. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in "listen-only" mode during the meeting.

Thank you,
Francis

From: Collins, Francis (NIH/OD) [E] <(b) (6)>
Sent: Wednesday, August 26, 2020 5:57 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> Gladman, Jordan (NIH/OD) [E] <(b) (6)> Allen-Gifford, Patrice (NIH/OD) [E] <(b) (6)>
Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Be sure to change the text of the e-mail from "tomorrow" to "today".

From: Collins, Francis (NIH/OD) [E]
Sent: Wednesday, August 26, 2020 5:56 AM
To: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Cc: Wholley, David (FNIH) [T] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)> ; Gladman, Jordan

(NIH/OD) [E] < (b) (6) Allen-Gifford, Patrice (NIH/OD) [E] (b) (6)
Subject: RE: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference

Yes, this note would be great. Looping in Exec Sec to ask that it be sent first thing this morning.

Francis

From: Parker, Ashley (NIH/OD) [E] < (b) (6) >
Sent: Tuesday, August 25, 2020 10:52 PM
To: Collins, Francis (NIH/OD) [E] (b) (6)
Cc: Wholley, David (FNIH) [T] (b) (6) Melencio, Cheryl (FNIH) [T] (b) (6) Gladman, Jordan (NIH/OD) [E] (b) (6)
Subject: Note to ICDs: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Importance: High

Hi Francis,

To ensure the ICDs receive the information for the ACTIV LT meeting tomorrow – would you like to forward the following to the ICD only list. Below is a draft note for consideration.

To: ICD-ONLY-L@LIST.NIH.GOV
Cc: Wholley, David (FNIH) [T] (b) (6) >; Melencio, Cheryl (FNIH) [T] < (b) (6)

Dear Colleagues,

As discussed during our conference call this afternoon, ICDs (**principals only please; no surrogates or additional staff**) are invited to join the virtual ACTIV leadership team meeting tomorrow August 26, 3:00-4:00pm. Please see the attached materials and link below. If you are able to join please ensure David Wholley and Cheryl Melencio know you are available to attend and please remain in “listen-only” mode during the meeting.

Thank you,
Francis

From: Melencio, Cheryl (FNIH) [T] (b) (6) **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Tuesday, August 25, 2020 9:47 PM
To: Austin, Christopher (NIH/NCATS) [E] < (b) (6) Bancel, Stephane
< (b) (6) >; Carter, Kara (b) (6) ; Cavaleri, Marco
< (b) (6) Cihlar, Tomas (b) (6) ; Collins, Francis (NIH/OD) [E]
< (b) (6) ; Corey, Larry < (b) (6) Culp, Michelle (NIH/OD) [E] (b) (6) ;
Disbrow, Gary (OS/ASPR/BARDA) (b) (6) Dolsten, Mikael (b) (6) Erbelding,
Emily (NIH/NIAID) [E] (b) (6) Erck, Stan (b) (6) ; Fauci, Anthony (NIH/NIAID) [E]
(b) (6) Freire, Maria (FNIH) [T] < (b) (6) ; Gadbois, Ellen (NIH/OD) [E]
>; Gibbons, Gary (NIH/NHLBI) [E] (b) (6) ; Hudson, Thomas
(b) (6) >; James, Stephanie (FNIH) [T] (b) (6) >; Johnson, Robert (OS/ASPR/BARDA)
(b) (6) >; Kramer, Lynn (b) (6) Lane, Cliff (NIH/NIAID) [E] (b) (6)
Lepore, John (b) (6) >; Marks, Peter (FDA/CBER) (b) (6) >; Marston, Hilary
(NIH/NIAID) [E] (b) (6) ; Mascola, John (NIH/VRC) [E] < (b) (6) Meeker, David
< (b) (6) Menetsky, Joseph (FNIH) [T] < (b) (6) Messonnier, Nancy
(CDC/DDID/NCIRD/OD) (b) (6) . Pandya, Hitesh (b) (6) >; Pangalos, Mene
< (b) (6) . Pao, William (b) (6) Parker, Ashley (NIH/OD) [E]
< (b) (6) Paul, Steve < (b) (6) ; Perlmutter, Roger < (b) (6)

Plenge, Robert < (b) (6) Plump, Andy < (b) (6) Rachel Ramoni
 < (b) (6) >; Rasi, Guido (b) (6) Reed, John (b) (6) >; Reese, David
 (b) (6) ; Rouse, Doris (b) (6) >; Santos, Michael (FNIH) [T] < (b) (6) Skovronsky,
 Daniel (b) (6) >; Stein, Peter (FDA/CDER) (b) (6) ; Stoffels, Paul
 < (b) (6) Tabak, Lawrence (NIH/OD) [E] < (b) (6) ; Talley, Michael
 (b) (6) ; Tsai, John (b) (6) >; Vessey, Rupert (b) (6) Virgin, Skip
 < (b) (6) Wholley, David (FNIH) [T] (b) (6) Woodcock, Janet (FDA/CDER)
 (b) (6) Young, John < (b) (6) Colvis, Christine (NIH/NCATS) [E]
 (b) (6) ; Desrosiers, Betsy (b) (6) Eric Hughes
 (b) (6) >; Jansen, Kathrin (b) (6) >; Kurilla, Michael (NIH/NCATS) [E]
 < (b) (6) Lowy, Douglas (NCI) < (b) (6) Read, Sarah (NIH/NIAID) [E] (b) (6) ;
 Young, John (b) (6)
 Cc: Adam, Stacey (FNIH) [T] (b) (6) ; Alvarez, Rosa (b) (6) ; Anderson, Margaret
 (b) (6) ; Chen, Helen < (b) (6) ; Elsaid, Olivia < (b) (6)
 Gonzalez, Nina (b) (6) Hawk, Harrison (b) (6) Menetski, Joseph (FNIH) [T]
 (b) (6) Santos, Michael (FNIH) [T] < (b) (6) ; Stratton, Benjamin (b) (6) >;
 btolman < (b) (6) Tountas, Karen (FNIH) [T] (b) (6) ; Wachtel, Jonathan
 (b) (6) >; Wholley, David (FNIH) [T] (b) (6) Anderson, James (NIH/OD) [E]
 (b) (6) ; Austin, Christopher (NIH/NCATS) [E] (b) (6) Burklow, John (NIH/OD) [E]
 (b) (6) Castillejos, Carlos (b) (6) ; Culp, Michelle (NIH/OD) [E]
 < (b) (6) FNIH Central Account < (b) (6) Freire, Maria (FNIH) [T]
 (b) (6) Gadbois, Ellen (NIH/OD) [E] (b) (6) , Hallett, Adrienne (NIH/OD) [E]
 < (b) (6) Lane, Cliff (NIH/NIAID) [E] < (b) (6) Myles, Renate (NIH/OD) [E]
 < (b) (6) Parker, Ashley (NIH/OD) [E] < (b) (6) Tabak, Lawrence (NIH/OD) [E]
 (b) (6) >; Wolinetz, Carrie (NIH/OD) [E] (b) (6) Burklow, John (NIH/OD) [E]
 < (b) (6) Gorman, Greta (FNIH) [T] < (b) (6) Hallett, Adrienne (NIH/OD) [E]
 < (b) (6) Meltzer, Abbey (FNIH) [T] (b) (6) Myles, Renate (NIH/OD) [E]
 < (b) (6) Wollnetz, Carrie (NIH/OD) [E] < (b) (6) >; Lucas Smalldon
 < (b) (6) >; Villafana, Tonya (b) (6) ; Brian Rosen
 < (b) (6)

Subject: Materials for August 26 ACTIV Partnership Leadership Team Teleconference
Importance: High

Dear Colleagues:

Please see attached the PowerPoint slides, including the agenda, for our meeting (via Zoom) from 3:00 – 4:00 PM Eastern U.S. time tomorrow, Wednesday August 26. (As a reminder, this meeting and future LT meetings are 60 minutes in length.) I have also attached notes from our July 29 Leadership Team meeting as well as our last ACTIV EC meeting on August 14.

The Zoom meeting information is:

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Please let Joe Menetski or Cheryl Melencio here at FNIH (copied) know if you are having any problems connecting. I look forward to a productive meeting.

Regards,

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

(b) (6)

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

To: Sizemore, Christine (NIH/FC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05494833e0fc47a9acac194cd338b201-csizemore]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283dba9e5098-mculp]; Brown, Jeremy (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce971eefec944a68a94add3b24835f5-brownj7]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Rosenberg, Yves (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a5cb3e9a3a2747c38c42f68f5c8e40cf-rosenbey]; Aggarwal, Neil (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c9de6615504ff9889f3b0c44a63526-aggarwalnr]; Reineck, Lora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a62d88ba0c3b44e3bb922236c61304b3-reineckla]; Timothy Burgess [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52e5e03dcbc847709eaab64457efa57e-TimothyBurg]; Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Collins, Sylvia (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Stein, Peter (FDA/CDER) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Judy Currier [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Butters, Joan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butters, Joan [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra [E] (b) (6) Eisner, Mark [E] (b) (6) Gottesdener, Keith [E] (b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes]; Judy Currier

[/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Kim, Elizabeth
 | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W
 | (b) (6) Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish
 | (b) (6) Peppercorn, Amanda | (b) (6)]; Poole, Mike
 | (b) (6) Proschan, Michael (NIH/NIAID) [E] | (b) (6) Read, Sarah
 (NIH/NIAID) [E] | (b) (6)]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Ste n, Peter (FDA/CDER)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim
 (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cd55cbf8eb9da-Tim.Buchman]; Collins, Sylva
 (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylva.Coll]; Amanda Peppercorn
 | (b) (6) Garner, Carl | (b) (6) Higgs, Elizabeth (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Jacqueline Kirchner
 | (b) (6) Berger, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigell]; Phillips, L Revell CIV
 DTRA RD (USA) | (b) (6) Petrovick, Martha - 0449 - MITLL | (b) (6)
 | (b) (6) Gadbois, El en (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisei]; Sizemore, Christine
 (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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 Waiker, Paula (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acb5fd03bcfd32930-walkerpl]; Kindzelski, Andrei
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Shipp, Allan
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Groesch, Mary (NIH/NHLBI)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Hoots, W. Keith
 (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Marston, Hilary
 (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Rubin, Danie B.

CC:

(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; James, Stephanie (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T]
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tountas, Karen (FNIH) [T]
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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(NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Colvis, Christine (NIH/NCATS)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
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| (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John
| (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6)
Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla
| (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; James, Stephanie (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan
| (b) (6) Tolman, Brett | (b) (6) Alvarez, Rosa | (b) (6)
Gonzalez, Nina | (b) (6) Dana Carluccio | (b) (6) Rose Li Central
Account | (b) (6) Margaret Anderson [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Lucas Smal don
| (b) (6) Stratton, Benjamin | (b) (6)
| (b) (6) Mollica, Linda /US | (b) (6) Qashu, Felicia (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Patterson, Amy
(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Rubin, Daniel B.
(FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Marston, Hilary
(NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Chen, Helen Q.
| (b) (6) Wung, Peter /US | (b) (6) Hoots, W. Keith (NIH/NHLBI) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=328221d5416d4fc59262c6c2eca59d4c-hootswk]; Groesch, Mary (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ab77a4c9bf499383186b9d9870344e-groeschm]; Shipp, Allan (NIH/NHLBI)
[E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=16001e8ab49c4489aef107bd0ce27715-shippa]; Kindzelski, Andrei

(NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8bda5194bdca4d2594626f6313d2db5c-kindzelskia]; Hone, David M (Dave)
CIV DTRA J9 (USA) | (b) (6) Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA)
| (b) (6) Elsaid, Olivia | (b) (6) Walker, Paula (NIH/NINDS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fbe81b9b832e40acbf5fd03bcfd32930-walkerp1]; Freire, Maria (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]

Start: 9/10/2020 5:00:00 PM
End: 9/10/2020 6:00:00 PM
Show Time As: Busy

Recurrence: (none)

From: Adam, Stacey (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=DCD875F0679648859E1CF101C0943414-ADAMSJ4]

Sent: 4/17/2020 7:46:51 PM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterton, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Draghia-Akli, Ruxandra | (b) (6) Eisner, Mark | (b) (6) Gottesd.ener, Keith
(b) (6) Hughes, Eric | (b) (6) Judy Currier
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurner.m]; Kim, Elizabeth | (b) (6) LaVange, Lisa | (b) (6) Levy, Elliot | (b) (6) Mellors, John W
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user257cb364]; Menon, Sandeep | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patel, Naimish | (b) (6) Peppercorn, Amanda | (b) (6) Poole, Mike
| (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Buchman, Tim (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00f8a853d8d740f8a8cdd55cbf8eb9da-Tim.Buchman]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia.Collins]; Amanda Peppercorn | (b) (6)

CC: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Desrosiers, Betsy (b) (6) Jansen, Kathrin | (b) (6) Kurilla, Michael (NIH/NCATS) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Young, John (b) (6) Biggs, Mary | (b) (6) Butcher, Tina | (b) (6)
Demarcus | (b) (6) Macone, Erin | (b) (6) Melencio, Cheryl (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Salathin, Carla | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Menetski, Joseph (FNIH) [T]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski.jp]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Wachtel, Jonathan (b) (6) Tolman, Brett | (b) (6) Alvarez, Rosa | (b) (6)
Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Dana Carluccio [dana.carluccio@rose-iassociates.com]; Rose Li Central Account | (b) (6) Anderson, Margaret | (b) (6) Lucas
Smalldon | (b) (6) |

Subject: ACTIV Therapeutics-Clinical Working Group - Meeting #3
Location: <https://fnih.zoom>. (b) (6)

Start: 4/23/2020 6:00:00 PM
End: 4/23/2020 7:00:00 PM
Show Time As: Tentative

Required Attendees: Bozzette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER). Draghia-Akli, Ruxandra; Eisner, Mark; Gottesdiener, Keith; Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep, Parker, Ashley (NIH/OD) [E]; Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylvia; Amanda Peppercorn

Optional Attendees: Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Doug as (NCI), Young, John; Biggs, Mary; Butcher, Tina; Demarcus; Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla; Tountas, Karen (FNIH) [T]; Menetski, Joseph (FNIH) [T]; James, Stephanie (FNIH) [T]; Wachtel Jonathan; Tolman, Brett; Alvarez, Rosa; Gonzalez, Nina; Dana Carluccio; Rose L. Central Account; Anderson, Margaret; Lucas Smalldon

Dear COVID PPP Therapeutics-Clinical WG Members and Co-Chairs from other WGs,

This will be the 3rd meeting of the TX-Clinical WG. We will update the invite with more information before the meeting.

Thanks,
Stacey

Join Zoom Meeting
<https://fnih.zoom>. (b) (6)

Meeting ID: (b) (6)
Password: (b) (6)
One tap mobile (b) (6)
US (New York)
US (Chicago)

Dial by your location

+	(b) (6)	US (New York)
+	(b) (6)	US (Chicago)
+1	(b) (6)	US
	(b) (6)	US
+	(b) (6)	US (Houston)
+	(b) (6)	US (San Jose)
+	(b) (6)	US (San Jose)

Meeting ID: (b) (6)
Password: (b) (6)
Find your local number: <https://fnih.zoom.us> (b) (6)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/14/2020 2:19:48 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolberg]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: RE: JAMA Viewpoint on ACTIV: please review

To be clear the new WG members are on this email thread below but we will need to add them to draft webpage once we have permission to list their names.

+ Abbey.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, May 14, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Myles, Renate (NIH/OD) [E] <(b) (6)>; Kolberg, Rebecca (NIH/OD) [E] <(b) (6)>
Cc: Burklow, John (NIH/OD) [E] <(b) (6)>; Tabak, Lawrence (NIH/OD) [E] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>; Melencio, Cheryl (FNIH) [T] <(b) (6)>
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis,

David forwarded the emails this morning. Please see below to make it easy to send.

I've pasted a slightly revised draft email OCPL provided (to also cc Renate, Abbey and David?). Renate – there are a few new members working group members, we can work together to update the list.

To:
Cc: Myles, Renate (NIH/OD) [E] <(b) (6)>; Meltzer, Abbey (FNIH) [T] <(b) (6)>; Wholley, David (FNIH) [T] <(b) (6)>
Bcc: Stoffels, Paul <(b) (6)>; Fauci, Anthony (NIH/NIAD) [E] <(b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Pao, William <(b) (6)>; Woodcock, Janet (FDA/CDER) <(b) (6)>; Arvin, Ann <(b) (6)>; Buchbinder, Susan <(b) (6)>; Corey, Larry <(b) (6)>; Davis, Mark <(b) (6)>; Emini, Emilio <(b) (6)>; Hanon, Emmanuel <(b) (6)>; Haynes, Barton <(b) (6)>

< (b) (6) Hotez, Peter (b) (6) >; Jansen, Kathrin (b) (6)
 Lanzavecchia, Antonio (b) (6) Lowy, Douglas (NIH/NCI) [E] (b) (6) >; Marks, Peter
 (FDA/CBER) < (b) (6) Mascola, John < (b) (6) Messonnier, Nancy
 (CDC/DDID/NCIRD/OD) (b) (6) Offit, Paul (b) (6) ; Parker, Ashley (NIH/OD) [E]
 < (b) (6) Santos, Michael (FNIH) [T] (b) (6) ; Santos, Nancy (b) (6)
 Schuitemaker, Hanneke (b) (6) ; Tartaglia, Jim (b) (6) Tolman, Brett
 < (b) (6) ; Zaks, Tal (b) (6) Qashu, Felicia (NIH/OD) [E] (b) (6)
 Michael, Nelson, (b) (6) >; Adam, Stacey (FNIH) [T] (b) (6) >; Bascles, Lionel
 < (b) (6) ; Cohen, Myron < (b) (6) Corey, Larry < (b) (6)
 Desrosiers, Betsy < (b) (6) Dickens, Jim (NIH/NCATS) [C] < (b) (6) ;
 Doroshow, James (NIH/NCI) [E] (b) (6) >, Goff, David (NIH/NHLBI) [E] < (b) (6) ; Heaton,
 Penny (b) (6) ; Kurilla, Mike (b) (6) ; Nayak, Seema (NIH/NIAID) [E]
 < (b) (6) ; Parker, Ashley (NIH/OD) [E] < (b) (6) Payton, Manzine
 < (b) (6) Resnansky, Laura < (b) (6) Srinivasan, Badhri
 (b) (6) >; Stein, Peter (FDA/CDER) < (b) (6) Karen (FNIH) [T]
 (b) (6) ; Vincent, Mike < (b) (6) >; Wachtel, Jonathan (b) (6)
 Woodcock, Janet (FDA/CDER) < (b) (6) (b) (6) Sizemore, Christine
 (NIH/FIC) [E] < (b) (6) Victoria Davey < (b) (6) Qashu, Felicia (NIH/OD) [E]
 (b) (6) >; Weinmann, (b) (6) ; Mensah, (b) (6) >;
 Adam, Stacey (FNIH) [T] < (b) (6) Bozzette, Sam (NIH/NCATS) [E] < (b) (6) Buchman, Tim
 (OS/ASPR/BARDA) (CTR) < (b) (6) Butters, Joan (b) (6) Currier, Judy
 (b) (6) , De Claro, R. Angelo (FDA/CDER) < (b) (6) Draghia-Akli, Ruxandra
 (b) (6) >; Eisner, Mark < (b) (6) Garner,
 Carlos (b) (6) >; Gottesdiener, Keith (b) (6) >; Hughes, Eric
 (b) (6) Kim, Elizabeth (b) (6) >; LaVange, Lisa (b) (6) ; Levy, Elliot
 < (b) (6) Mellors, John < (b) (6) Menon, Sandeep (b) (6) >; Parker,
 Ashley (NIH/OD) [E] < (b) (6) >; Patel, Naimish (b) (6) Peppercorn, Amanda
 < (b) (6) Poole, Mike < (b) (6) Proschan, Michael
 < (b) (6) Read, Sarah (b) (6) ; Santos, Michael (FNIH) [T] (b) (6) >Shen,
 Yuan Li (FDA/CDER) (b) (6) Stein, Peter (FDA/CDER) (b) (6) Higgs, Elizabeth
 (b) (6) >; Koroshetz, Walter (b) (6) ; Farley, John (b) (6)
 (b) (6) ; Qashu, Felicia (b) (6) >; Burgess,
 Timothy (b) (6) >; Reineck, Lora (b) (6) ; Aggarwal, Neil < (b) (6)

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed as part of the ACTIV membership.**

Thanks,
Francis

Francis Collins, MD, PhD
NIH Director

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-ME.ENCIOC]
Sent: 5/11/2020 4:46:34 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Hardesty, Rebecca (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21465ceb763947408d209aaabf10af70-hardestyrs]
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

I'll send her the invite and copy her assistant, Rebecca.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
(b) (6)

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 11, 2020 12:46 PM
To: Wood, Gretchen (NIH/OD) [E] <(b) (6)> Melencio, Cheryl (FNIH) [T] <(b) (6)>
Cc: Hardesty, Rebecca (NIH/OD) [C] <(b) (6)>
Subject: RE: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Hi Gretchen and Cheryl,

Dr. Carrie Wolinetz would like to join this meeting. Cheryl -- should I forward the invite or would you prefer to add on your end?

Thank you,
Ashley

From: Wood, Gretchen (NIH/OD) [E] <(b) (6)>
Sent: Monday, May 11, 2020 9:23 AM
To: Collins, Francis (NIH/OD) [E] <(b) (6)>; Fauci, Anthony (NIH/NIAID) [E] <(b) (6)>; Gibbons, Gary (NIH/NHLBI) [E] <(b) (6)>; Stoffels, Paul <PSI> <(b) (6)> Pao, William
<(b) (6)>; Dolsten, Mikael <(b) (6)>; Colvis, Christine (NIH/NCATS) [E]
<(b) (6)>; Desrosiers, Betsy <(b) (6)> Hughes, Eric
<(b) (6)> Jansen, Kathrin <(b) (6)> Kurilla, Michael (NIH/NCATS) [E]
<(b) (6)> Lowy, Douglas (NCI) <(b) (6)> Read, Sarah (NIH/NIAID) [E] <(b) (6)>;
Young, John <(b) (6)>

Cc: Wholley, David (FNIH) [T] < (b) (6) Menetski, Joseph (FNIH) [T] < (b) (6) Adam, Stacey (FNIH) [T] (b) (6) Tountas, Karen (FNIH) [T] (b) (6) ; Santos, Michael (FNIH) [T] < (b) (6) Freire, Maria (FNIH) [T] (b) (6) Tabak, Lawrence (NIH/OD) [E] (; Lane, Cliff (NIH/NIAID) [E] (b) (6) >; Parker, Ashley (NIH/OD) [E] (b) (6) Anderson, James (NIH/OD) [E] (b) (6) ; Austin, Christopher (NIH/NCATS) [E] (b) (6) >; Melencio, Cheryl (FNIH) [T] (b) (6) >
Subject: Re: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Good morning,

Please mark your calendars for Wednesday, May 13, from 8:00 AM-9:00 AM ET for this call. A calendar invitation will be shared with you soon.

With very best wishes,

Gretchen

From: Francis Collins (b) (6)
Date: Saturday, May 9, 2020 at 1:07 PM
To: Francis Collins < (b) (6) Anthony Fauci < (b) (6) "Gibbons, Gary (NIH/NHLBI) [E]" < (b) (6) , " (b) (6) < (b) (6) . Gretchen Wood < (b) (6) "Pao, William" < (b) (6) , " (b) (6) < (b) (6) "Colvis, Christine (NIH/NCATS) [E]" < (b) (6) , "Desrosiers, Betsy" (b) (6) . "Hughes, Eric" < (b) (6) "Jansen, Kathrin" < (b) (6) "Kurilla, Michael (NIH/NCATS) [E]" < (b) (6) . "Lowy, Douglas (NCI)" < (b) (6) "Read, Sarah (NIH/NIAID) [E]" < (b) (6) . "Young, John" < (b) (6)
Cc: David Wholley < (b) (6) , "Menetski, Joseph (FNIH) [T]" < (b) (6) "Adam, Stacey (FNIH) [T]" (b) (6) , "Tountas, Karen (FNIH) [T]" < (b) (6) "Santos, Michael (FNIH) [T]" < (b) (6) Maria Freire < (b) (6) . "Tabak, Lawrence (NIH/OD) [E]" (b) (6) >, "Lane, Cliff (NIH/NIAID) [E]" (b) (6) >, Ashley Parker < (b) (6) James Anderson < (b) (6) "Austin, Christopher (NIH/NCATS) [E]" (b) (6) , "Melencio, Cheryl (FNIH) [T]" (b) (6) Gretchen Wood (b) (6)

Subject: Time sensitive -- ACTIV mtg with Exec Comm and WG co-chairs

Dear ACTIV Executive Committee Members and Working Group Co-Chairs:

Although our next formal ACTIV EC meeting is not scheduled until May 20, I am aware of some concerns that are being voiced among our Working Group members. Some of those focus on the next steps for ACTIV, and especially about implementation of the plans these groups have been working so hard to put together. There are also concerns about how we should best communicate across our partnership and coordinate with the many parallel (and in some cases conflicting) efforts that have emerged elsewhere—including among our own ACTIV members.

These are all very valid issues, and I believe they should be discussed by our dedicated team sooner rather than later. A meeting of the minds is particularly timely now, in the wake of a successful Leadership Team call on Wednesday and the establishment just this week of an Executive Committee to guide us moving forward. Therefore, I would like to make it a priority that the EC and the Working Group co-Chairs meet early next week to discuss and sync up on these important issues. Gretchen Wood on my staff will work with Cheryl Melencio at FNIH to reach out to you to get a suitable hourlong virtual conference set up—a morning meeting would make it easier to include Tony Fauci (because of White House duties in the afternoon) and Paul Stoffels (because of European time zones).

Thanks for all you are doing for the cause, and best regards,

Francis

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415B886087D08B628E6F-ME_ENCIOC]
Sent: 11/12/2020 5:10:25 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Bancel, Stephane [(b) (6) Carter, Kara [(b) (6) Cavaleri, Marco [(b) (6) Cihlar, Tomas [(b) (6) Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Corey, Larry [(b) (6) Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Do sten, Mikael [(b) (6) Erbelding, Emily (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbeldinge]; Erck, Stan [(b) (6) Fauci, Anthony (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Hudson, Thomas [(b) (6) James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Kramer, Lynn [(b) (6) Lane, Cliff (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Lepore, John [(b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Marston, Hilary (NIH/NIAD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffb9ae95d631116f3-marstonhd]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Meeker, David [(b) (6) Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Pandya, Hitesh [(b) (6) Pangalos, Mene [(b) (6) Pao, William [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Paul, Steve [(b) (6) Perlmutter, Roger [(b) (6) Plenge, Robert [(b) (6) Plump, Andy [(b) (6) Rachel Ramon [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3f6cb5237a44b75887b8a1ca1f9bb91-Rachel.Ramon]; Rasi, Guido [(b) (6) Reed, John [(b) (6) Reese, David [(b) (6) Rouse, Doris [(b) (6) Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Skovronsky, Daniel [(b) (6) Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Stoffels, Paul [(b) (6) Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabaki]; Tal ey, Michael [(b) (6) Tsai, John [(b) (6) Vessey, Rupert [(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Young, John

(b) (6) Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis], Desrosiers, Betsy
 | (b) (6)]; Eric Hughes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f97951a53cd54153b5daa9d99ad4ec90-EricHughes], Jansen, Kathrin
 | (b) (6) Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lowy, Douglas (NCI)
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54fa75fe6e304e34ba567c66b832baa0-drl.helix.n]; Read, Sarah (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]
 CC: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Burklow, John
 (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Carluccio, Dana
 | (b) (6) Castillejos, Carlos | (b) (6) FNIH Central Account
 | (b) (6) Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-halletta]; Myles, Renate (NIH/OD) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolnetz, Carrie (NIH/OD)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolnetzcd]; Adam, Stacey (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Margaret Anderson
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab9a138f1e284c689fedfb10b8cc5295-marganderso]; Appell, Evan
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Chen, Helen Q.
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Hawk, Harrison
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Menderson, Jesse (b) (6) asorosa
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Stratton, Benjamin
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; btolman [/o=ExchangeLabs/ou=Exchange Administrative
 Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; Tountas, Karen (FNIH) [T]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan
 (b) (6)]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanm]; Metzger, Abbey (FNIH)
 [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Austin, Sarah (NIH/NIAID)
 [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; Barasch, Kimberly
 (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea5fad4c52f64f80b7daee4982ae495f-baraschk]; Bell, Julie
 (b) (6)]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Carver, Trea (NIH) [C]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Caulfield, Anita
 | (b) (6) Coan, Amanda | (b) (6) Conrad, Patricia (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ea3e3ea7daa432887495d6825c9e588-conradpa]; Dimishkov, Roxanne
 (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d8415061971c493881c08c8c6cd75fb8-dimishkovrd]; Edl, Susan
 | (b) (6) Fuhrer, Nicole | (b) (6) Giorgi, Sara | (b) (6)
 Hoban, Michelle | (b) (6) Hoffstetter, Renata (FNIH) [T] [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e9758570bf4ca08552ea377170ec2a-hoffstetter];

Iberdemaj, Vaide | (b) (6) Jenkins, Christine S. | (b) (6) Krack, Kimberly [kimberly]; (b) (6) Lagos, Enrique (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae9041ab27204d83b06752f67a44b0d1-lagos]; Lever, Susan | (b) (6) McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Minnich, Beth | (b) (6) Perala, Mie | (b) (6)]; Protasiewicz, Ann | (b) (6) Riccobene, Kim | (b) (6) Riffin, Mary | (b) (6) Ripley, Nadege | (b) (6) Schuster, Donna | (b) (6) Sepulveda, Dorina (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=675efcc8cf7b4f6986d1eb3c3ed1fd96-sepulvedade]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Suhana, Tina (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e062bf05a14748ba3d9fb3e468057-esuhana]; Thomas, Ashley (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bcd5d3f7c1e4309a251d013e1cc89b0-Ashley.Thom]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Hughes, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e11e04daa2b44dea1a06ce7ab21cb1a-hugneskp]; Taja li, Ada (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fd4747b0d954e27855c241b28562547-tajallian]; Togashi, Mieko (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=136a73bd42274938aa467e738767f83e-togash m]; Underwood, Nancy | (b) (6) Zottoli, Jessica | (b) (6)

Subject: ACTIV Leadership Team Meeting #11

Location: <https://fnih.zoom.us/> (b) (6)

Start: 12/16/2020 3:00:00 PM

End: 12/16/2020 4:00:00 PM

Show Time As: Busy

Required Attendees: Austin, Christopher (NIH/NCATS) [E]; Bancel, Stephane; Carter, Kara; Cavaleri, Marco; Cihlar, Tomas; Collins, Francis (NIH/OD) [E]; Corey, Larry; Culp, Michelle (NIH/OD) [E]; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbeling, Emily (NIH/NIAID) [E]; Erck, Stan; Fauc, Anthony (NIH/NIAID) [E]; Gadbois, Ellen (NIH/OD) [E]; G bbons, Gary (NIH/NHLBI) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Lepore, John; Marks, Peter (FDA/CDER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD); Pandya, Hitesh; Pangalos, Mene; Pao, William; Parker, Ashley (NIH/OD) [E]; Paul, Steve; Perlmutter, Roger; Plenge, Robert; Plump, Andy; Ramoni, Rachel; Ras, Guido; Reed, John; Reese, David; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Talley, Michael; Tsai, John; Vessey, Rupert; Wholley, David (FNIH) [T]; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]

Optional Attendees: Anderson, James (NIH/OD) [E]; Burklow, John (NIH/OD) [E]; Carluccio, Dana; Castillejos, Carlos; FNIH Central Account; Hallett, Adrienne (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Wolinetz, Carrie (NIH/OD) [E]; Adam, Stacey (FNIH) [T]; Anderson, Margaret; Appell, Evan; Chen, Helen; Connelly, Sarah; Gonzalez, Nina; Hawk, Harrison; Mendelson, Jesse; Sorosa, Alex; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Gorman, Greta (FNIH) [T]; Meltzer, Abbey (FNIH) [T]; Austin, Sarah (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Bell, Julie; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Caulfied, Anita; Coan, Amanda; Conrad, Patricia (NIH/NIAID) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Edl, Susan; Fuhrer, Nicole; Giorg, Sara; Hoban, Michelle; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Jenkins, Christine S.; Krack, Kimberly; Lagos, Enrique (NIH/NCATS) [E]; Lever, Susan; McManus, Ayanna (NIH/OD) [E]; Minnich, Beth; Perala, Mie; Protasiewicz, Ann; Riccobene, Kim; Riffin, Mary; Ripley, Nadege; Schuster, Donna; Sepulveda, Donna (FNIH) [T]; Simon, Dina (NIH/OD) [C]; Suhana, Tina

(NIH/VRC) [E]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; Hughes, Karen (NIH/OD) [E]; Tajalli, Ada (NIH/OD) [E]; Togashi, Mieko (NIH/NCI) [E]; Underwood, Nancy; Zottoli, Jessica

Joseph Menetski is inviting you to a scheduled Zoom meeting.

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From: Santos, Michael (FNIH) [T] [/o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]

Sent: 6/30/2020 7:18:04 PM

To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr];
 (b) (6) Lowy, Douglas (NIH/NCI) [E] | (b) (6) (b) (6)
 Arvin, Ann | (b) (6) Beth Bell | (b) (6) | (b) (6)
 (b) (6) Cavaleri Marco | (b) (6) (b) (6)
 (b) (6) (b) (6) Greg Glenn | (b) (6)
 (b) (6) Haynes, Barton | (b) (6) (b) (6) (b) (6)
 Marks, Peter (FDA/CBER) | (b) (6) Mascola, John (NIH/VRC) [E] | (b) (6)
 Messonnier, Nancy (CDC/DDID/NCIRD/OD) | (b) (6) Nelson Michael | (b) (6) il);
 Offit, Paul | (b) (6) Seals, Jonathan (OS/ASPR/BARDA) | (b) (6)
 (b) (6) (b) (6) (b) (6) Tal Zaks
 | (b) (6)
CC: Tolman, Brett | (b) (6) (b) (6) Hopps, Markay | (b) (6)
 Kozlowski, Mary (NIH/NCI) [C] | (b) (6) | Johnson, Maureen (NIH/NCI) [E]
 | (b) (6) (b) (6) Jeneffer Haynes | (b) (6) |
 (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E]
 | (b) (6) (b) (6) Isabel Ramsey | (b) (6) Parker,
 Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Henry
 (NIH/NIAID) [E] | (b) (6) Qashu, Felicia (NIH/OD) [E] | (b) (6) Culp, Michael
 (NIH/OD) [E] | (b) (6) Gadbois, Ellen (NIH/OD) [E] | (b) (6) Wholley, David (FNIH) [T]
 | (b) (6) Melencio, Cheryl (FNIH) [T] | (b) (6) Menetski, Joseph (FNIH) [T]
 | (b) (6) Adam, Stacey (FNIH) [T] | (b) (6) Tountas, Karen (FNIH) [T] | (b) (6)
 James, Stephanie (FNIH) [T] | (b) (6) Colvis, Christine (NIH/NCATS) [E] | (b) (6)
 Desrosiers, Betsy | (b) (6) Hughes, Eric | (b) (6) Kurilla, Michael
 (NIH/NCATS) [E] | (b) (6) Read, Sarah (NIH/NIAID) [E] | (b) (6) Paul Gillard
 | (b) (6) Hamilton, Holli (OS/ASPR/BARDA) | (b) (6) Modjarrad, Kayvon CIV
 USARMY MEDCOM WRAIR (USA) | (b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD)
 | (b) (6) Verani, Jennifer R. (CDC/DDID/NCIRD/DBD) | (b) (6) Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD) | (b) (6) 'Wachtel, Jonathan' | (b) (6) Stratton, Benjamin
 | (b) (6) rose. (b) (6) dana.carr | (b) (6) Bethany Stokes
 | (b) (6) Kathleen Callahan | (b) (6) Gallo, Robert
 | (b) (6) Kottilli, Shyamasundaran | (b) (6) Chumakov, Konstantin
 (FDA/CBER) | (b) (6) Konstantin Chumakov | (b) (6) Miller, Elissa
 | (b) (6) Pfeiffer, Frank | (b) (6) Jacqueline Miller
 | (b) (6) Jessica Cowden | (b) (6) Arvin, Ann
 | (b) (6) Young, John | (b) (6) Kathleen Neuzil
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 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 Anderson, Margaret | (b) (6)

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex>. (b) (6)

Start: 7/13/2020 4:00:00 PM

End: 7/13/2020 5:00:00 PM

Show Time As: Busy

Required Attendees: Santos, Michael (FNIH) [T]; (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6)
 Arvin, Ann; Beth Bell | (b) (6) (b) (6) Cavaleri Marco; (b) (6)
 (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,

Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E];
 Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael; Offit, Paul, (b) (6) Seals, Jonathan
 (OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay, Kozlowski, Mary (NIH/NCI) [C]; Johnson, Maureen
 (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
 (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
 Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
 Gadbois, Elen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
 Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
 Desrosiers, Betsy, Hughes, Eric; Kunlla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
 Gillard; Hamilton, Holli (OS/ASPR/BARDA); Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD); Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
 (b) (6) (b) (6) Bethany Stokes; Kathleen Callahan; Gallo,
 Robert; Kottlil, Shyamasundaran; Chumakov, Konstantin (FDA/CBER); Konstantin Chumakov; Miller, Elissa; Pfeiffer,
 Frank; Jacqueline Miller; Cowden, Jessica J Col USAF AFMSA (USA); Ann Arvin

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Sent: 5/16/2020 8:37:37 PM

To: Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Butterson, Joan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=219ecac4faae4ebab8a45ce8ee2490c3-joan_butter]; Collins, Sylvia (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b8f588067140fe988f0832c2387725-Sylvia Colli]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; De Claro, R. Angelo (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c495c3ee25ca461ba6a829b124062448-DECLAROR.fd]; Mark Eisner | (b) (6) Keith Gottesdiener | (b) (6) Eric Hughes | (b) (6) LaVange, Lisa M | (b) (6) Elliott Levy | (b) (6) Sandeep Menon | (b) (6) Amanda Peppercorn | (b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Amanda Peppercorn | (b) (6) Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Shen, Yuan Li (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae30a02e983e4e8a979dfec7257a1802-shenyu.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; Vincent, Michael | (b) (6) Wung, Peter /US | (b) (6) Karen Lynn Price | (b) (6) Pamela Tenaerts, M.D. | (b) (6) Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Burgess, Timothy | (b) (6) Beumont-Mauviel, Maria [JRDU] | (b) (6) Peeters, Monika [JRDBE] | (b) (6) Woodfall, Brian [JRDU] | (b) (6)]; Van Heeswijk, Rolf [JRDBE] | (b) (6)

CC: Mary Biggs | (b) (6) Demarcus | (b) (6) Macone, Erin | (b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan | (b) (6) Elizabeth Kim | (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Butcher, Tina | (b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc128414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Note about ACTIV TX-Clinical Master Protocol Subgroup Meeting #19

Dear ACTIV TX-Clinical Master Protocol Subgroup,

Similarly to my last note, many of you will see this meeting disappear from your calendar as well. We will be repurposing this for another discussion with the SARS-CoV-2 neutralizing mAbs subteam.

Thank you for your understanding and we look forward to updating you all on our progress on Thursday and Friday.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

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From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
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(b) (6) (b) (6) Gruber, Marion (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebf7a8eb8dd541b2883a966ea5afd809-GRUBER.fda];
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha];
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(b) (6) Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcd28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH)
[T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Laurent Humeau
[(b) (6) Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
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(b) (6) Hotez, Peter Jay [(b) (6)]; (b) (6) Tal Zaks
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(b) (6) Gebo, Kelly (NIH/OD) [G] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=009cf99ae63f4f71b5b1204a73ded609-geboka]; Jacqueline Miller
[(b) (6) François P Roman [(b) (6) Culp, Michelle (NIH/OD) [E]
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Mart n, Stacey
(CDC/DDID/NCEZID/DVBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffe35bbdbfbd495f97712313bedcaecc-ZMT0]; McNamara, Lucy Alexandra
(CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94d2e362b03243568fa31c3d23550095-xdf4]; Schully, Sheri (NIH/OD) [E]
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(HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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 | (b) (6) (b) (6) Follmann, Dean (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=42106b36984344e0914421f5fe408e7b-dfollmann]; Baden, Lindsey
 Robert, M.D. | (b) (6)
CC: btolman [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7b137a1e]; (b) (6) (b) (6) ;
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 (b) (6) Isabel Ramsey | (b) (6) Sridhar, Saranya /US
 | (b) (6) Brian Rosen | (b) (6) Cheryl Keech | (b) (6) Sadoff,
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 (b) (6) (b) (6) Shannon Devine | (b) (6)

Subject: Agenda for the Vaccines Clinical Trials Sub-Group meeting tomorrow

Dear Vaccines Clinical Trials Sub-Group,

We're looking forward to our meeting tomorrow (Monday), at 12pm ET (9am PT / 6pm CST).

The topic for discussion will be the potential to conduct blinded cross-overs of placebo control group phase 3 trial participants to active controls. We will be joined by Dean Follmann of NIAID and Lindsey Baden of Harvard who will present potential approaches for discussion.

Please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Sunday, November 22, 2020 7:09 PM
Subject: Notes from the Vaccines Clinical Trials Sub-Group meeting

Dear Vaccines Clinical Trials Sub-Group,

Thank you for your participation in our last meeting, and particular thanks to Larry, Audrey, and Holly for leading the discussion.

Notes from the meeting with the presentation embedded are attached. As a reminder, if you have additional feedback for the group working on the design of this study, please either reach out to them directly or send it to us and we will pass it along.

We welcome your questions or suggestions any time.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Santos, Michael (FNIH) [T]
Sent: Wednesday, November 18, 2020 8:02 AM
Subject: Agenda for the Vaccines Clinical Trials Sub-Group meeting today

Dear Vaccines Clinical Trials Sub-Group,

We're looking forward to our meeting today, at 1pm ET (10am PT / 7pm CST).

The topic for discussion will be the potential to evaluate the impact of vaccines on transmission. We will be joined by Audrey Pettifor of UNC and Holly Janes of Fred Hutch, who with Larry Corey will present potential approaches for discussion.

Please feel free to reach out with any questions or suggestions.

Best regards,
Brett and Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
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Start: 2/18/2021 6:00:00 PM
End: 2/18/2021 7:00:00 PM

Recurrence: (none)

Required Attendees: Adam, Stacey (FNIH) [T]; Bozette, Sam (NIH/NCATS) [E]; Butterson, Joan; De Claro, R. Angelo (FDA/CDER); Draghia-Akli, Ruxandra; Gottesdiener, Keith, Hughes, Eric; Judy Currier; Kim, Elizabeth; LaVange, Lisa; Levy, Elliot; Mellors, John; Menon, Sandeep; Parker, Ashley (NIH/OD) [E], Patel, Naimish; Peppercorn, Amanda; Poole, Mike; Proschan, Michael; Read, Sarah; Santos, Michael (FNIH) [T]; Shen, Yuan Li (FDA/CDER); Stein, Peter (FDA/CDER); Wholley, David (FNIH) [T]; Buchman, Tim (OS/ASPR/BARDA) (CTR); Collins, Sylva (FDA/CDER); Amanda Peppercorn; Garner, Carl; Higgs, Elizabeth (NIH/NIAID) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Burgess, Timothy; Reineck, Lora (NIH/NHLBI) [E]; Aggarwal, Neil (NIH/NHLBI) [E]; Rosenberg, Yves (NIH/NHLBI) [E]; Goff, David (NIH/NHLBI) [E] [(b) (6) Brown, Jeremy (NIH/NINDS) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Jacqueline Kirchner;

Optional Attendees: Beigel, John (NIH) [E]; Phillips, L Revell CIV DTRA RD (USA); Petrovick, Martha - 0449 - MITLL;
(b) (6) Sizemore, Christine (NIH/FIC) [E]; Larry Tsai; Wung, Peter K
Colvis, Christine (NIH/NCATS) [E]; Jansen, Kathrin; Lowy, Douglas (NCI); Young, John; Biggs, Mary; Butcher, Tina;
Demarcus, Macone, Erin; Melencio, Cheryl (FNIH) [T]; Salathin, Carla, Menetski, Joseph (FNIH) [T]; Dana Carluccio;
Rose Li Centra Account; Lucas SmaIdon; (b) (6) Mollica, Linda /US; Qashu, Felicia (NIH/OD)
[E]; Patterson, Amy (NIH/NHLBI) [E]; Rubin, Daniel B. (FDA/CDER); Marston, H lary (NIH/N AID) [E]; Chen, Helen Q.;
Hoots, W. Keith (NIH/NHLBI) [E]; Groesch, Mary (NIH/NHLBI) [E]; Shipp, Allan (NIH/NHLBI) [E]; Kindzelski, Andrei
(NIH/NHLBI) [E]; Hone, David M (Dave) CIV DTRA J9 (USA); Reisler, Ronald B CTR USARMY DOD JPEO CBRND (USA);
Walker, Paula (NIH/NINDS) [E]; Sorosa, Alex David; Lumsden, Joanne (NIH/NCATS) [C]; Lerner, Andrea (NIH/NIAID)
[E]; Embry, Alan (NIH/NIAID) [E]; Samuel Brown; Caroline Sferrazza

From: Santos, Michael (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AB38CB6836DE44E18EF4CC6952F65F80-SANTOSMR]
Sent: 6/30/2020 7:17:58 PM
To: (b) (6) Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowy]; (b) (6) Arvin, Ann [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bbf6108d53148f684dad333fce983de-aarvin.stan]; Beth Bell (b) (6) (b) (6) (b) (6) Cavaleri Marco (b) (6) (b) (6) (b) (6) Greg Glenn (b) (6) (b) (6) Haynes, Barton [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d4a05845b5b4069ad0447fb60ebfa79-hayne002.mc]; (b) (6) (b) (6) Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527bdba2b4a86b8d72f06b813d471-MarksP.fda]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Messonnier, Nancy (CDC/DDID/NCIRD/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=441f65db836c4a89a42aecb9a0d9b96c-NAR5]; Nelson Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Offit, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb9cc56f8be4598a57b423d484dcf9f-offit.email]; HSchuite@rts.jnj.com; Seals, Jonathan (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a87d49ccb4e3caaf5eb5d3586b1cc-Jonathan.Se]; (b) (6) (b) (6) Tal Zaks (b) (6) (b) (6) Tolman, Brett (b) (6) (b) (6) Hopps, Markay (b) (6) (b) (6) Kozlowski, Mary (NIH/NCI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15373a5a1d8a4fa89d49ba9c8561cc94-kozlowskimt]; Johnson, Maureen (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0cb4ad1bebe64791b0415a7eb4bf71db-johnsonr]; (b) (6) Jeneffer Haynes (b) (6) (b) (6) (b) (6) Austin, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=292fcb760f9f4f199ebe343e08ef1781-austinsj]; (b) (6) Isabel Ramsey (b) (6) (b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Marston, Hiary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Gadbois, Ellen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0243d1d6e6f248268d2edec566c26c2a-gadboisel]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetski]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group

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 (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Read, Sarah (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Young, John
 [(b) (6) Paul Gillard] (b) (6) Hamilton, Holli (OS/ASPR/BARDA)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=a28fc2f8eb134b00b5eaa4222d0576cc-Holli Hamil]; Modjarrad, Kayvon CIV
 USARMY MEDCOM WRAIR (USA) [(b) (6) Kathleen Neuzil [/o=ExchangeLabs/ou=Exchange
 Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33958e1252cf4266bffc8d94988f5715-kneuzil.com];
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be29b344ba14363bdecaa43582ca226-ZHA6]; Verani, Jennifer R.
 (CDC/DDID/NCIRD/DBD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c249692151d46d6ac80cb28ada3d3a0-qzr7]; Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD) [/o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8d079e00a5649639c6f1425f3bb075f-nax3]; Gonzalez, Nina
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d];
 'Wachtel, Jonathan' [(b) (6) Stratton, Benjamin] (b) (6) Anderson, Margaret
 [(b) (6) (b) (6) (b) (6) Bethany Stokes
 [(b) (6) Kathleen Callahan] (b) (6)

Subject: ACTIV Vaccines Working Group meeting

Location: Webex: <https://nih.webex.com/> (b) (6)

Start: 7/8/2020 5:15:00 PM

End: 7/8/2020 6:15:00 PM

Show Time As: Tentative

Required Attendees: (b) (6) Lowy, Douglas (NIH/NCI) [E]; (b) (6) Arvin, Ann; Beth Bell
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 (b) (6) (b) (6) Greg Glenn; (b) (6) Haynes,
 Barton; (b) (6) (b) (6) Marks, Peter (FDA/CBER); Mascola, John (NIH/VRC) [E],
 Messonnier, Nancy (CDC/DDID/NCIRD/OD); Nelson Michael, Offit, Paul; (b) (6) Seals, Jonathan
 (OS/ASPR/BARDA); (b) (6) (b) (6) Tal Zaks
Optional Attendees: Tolman, Brett; (b) (6) Hopps, Markay; Kozlowsk, Mary (NIH/NCI) [C]; Johnson, Maureen
 (NIH/NCI) [E]; (b) (6) Jeneffer Haynes; (b) (6) (b) (6)
 (b) (6) Austin, Sarah (NIH/NIAID) [E]; (b) (6) Isabel Ramsey; Parker,
 Ashley (NIH/OD) [E]; Marston, Hilary (NIH/NIAID) [E]; Qashu, Felicia (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E];
 Gadbois, Ellen (NIH/OD) [E]; Wholley, David (FNIH) [T]; Melencio, Cheryl (FNIH) [T]; Menetski, Joseph (FNIH) [T];
 Adam, Stacey (FNIH) [T]; Tountas, Karen (FNIH) [T]; James, Stephanie (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E];
 Desrosiers, Betsy, Hughes, Eric, Kurilla, Michael (NIH/NCATS) [E]; Read, Sarah (NIH/NIAID) [E]; Young, John; Paul
 Gillard; Hamilton, Holli (OS/ASPR/BARDA), Modjarrad, Kayvon CIV USARMY MEDCOM WRAIR (USA); Kathleen Neuzil;
 Schrag, Stephanie (CDC/DDID/NCIRD/DBD); Verani, Jennifer R. (CDC/DDID/NCIRD/DBD); Thornburg, Natalie
 (CDC/DDID/NCIRD/DVD), Gonzalez, Nina; Wachtel, Jonathan; Stratton, Benjamin; Anderson, Margaret;
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Sent: 5/19/2020 12:40:55 AM
To: Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Eric Hughes [(b) (6) LaVange, Lisa M [(b) (6) Sandeep Menon [(b) (6) Proschan, Michael (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45059209b4468bb4ba02b0dfbbb3e4-proscham]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Price, Dionne (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583eced842c44b18bb6fcd3820bee21-priced.fda]; Rubin, Daniel B. (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=35c2891059134111a3ed28f929042aad-RUBIND.fda]; Farley, John (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40b4c4456b14464788f31fe7bcaa09bc-FARLEYJ.fda]; Karen Lynn Price [(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) wil (b) (6) : Eron, Joe (b) (6) Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Roa, Jhoanna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=545d85545ba74b29bc4cd4f75ef659f5-jroa.s-3.co]; (b) (6) Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]
CC: Demarcus [(b) (6) Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan (b) (6) Elizabeth Kim [(b) (6) Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Jhoanna Roa [(b) (6) Eron, Joseph J Jr (b) (6)]; Smith, David [(b) (6) Paul Klekotka [(b) (6) Ajay Nirula [(b) (6)]
Subject: Follow-up from ACTIV TX-Clinical Master Protocol Outpatient mAbs Writing Team Meeting #1
Attachments: a5401-d03-activ-051620.docx; ACTIV_Therapeutics-Clinical_MP Sub-Group Meeting 18May2020_Key Takeaways.pdf

Dear ACTIV Outpatient mAbs Writing Team,

Please find attached the notes from today's meeting that Elizabeth did a great job in capturing. While I know we would have liked to make more forward headway, I do think our conversations put us on the right path to take the next step forward.

Per the action items:

(b) (4)

In addition, we wanted to set another meeting of these team for tomorrow. I have discussed with Karen and Lisa and they think they could have some thoughts together for the group's response by 4pm tomorrow. **Would this group be able to meet from 4-5pm ET tomorrow?**

Finally, the ACTG team that has been working on the base protocol would like to hear any other feedback not covered in the action items above from the group, so if you all can review and be ready to provide thoughts or send them in redline and comments ahead of the meeting, that would be perfect. (Document attached once again for ease of reference.)

Once again, thank you all for being willing to come together and get this protocol revised to fit the capacity needs of this new venture!

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/29/2020 2:07:00 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabc42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: FW: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions
Attachments: Coagulation COVID19 panel roster BARDA30 April 2020 v042620.docx; Pulmonary-ARDS Expert Panel.docx; renal pane roster.docx; Immunoinflammatory panel roster.docx

News—members of our TX-Clinical WG have been invited to an ad hoc BARDA panel to look at anticoagulants that could be accelerated. Cliff, I thought you might be particularly interested in hearing this given your recent comments in our war room calls. By the way Tim Buchman has been a very active and vocal participant on the ACTIV WG calls.

From: Adam, Stacey (FNIH) [T] <(b) (6)>
Sent: Wednesday, April 29, 2020 9:56 AM
To: Wholley, David (FNIH) [T] <(b) (6)>
Subject: FW: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions

Hi David,

Per my last note, here is the updated information and invite from our BARDA rep.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: (b) (6) Mobile: (b) (6)

From: Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)>
Sent: Wednesday, April 29, 2020 9:51 AM
To: Read, Sarah (NIH/NIAID) [E] <(b) (6)> Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> Hughes, Eric <(b) (6)>
Subject: RE: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions

Dear Sarah and Walter, cc: Eric and Stacey,

Good morning, no problem.

Let me also mention something else that may be useful to you.

For the past three weeks, I have been assembling panels of national/international experts for BARDA to discuss "where things stand" and "what's needed" assorted by organ systems. These are truly blue ribbon panels. Thus far there are four: immunoinflammatory; renal; pulmonary/ARDS; and coagulation.

By happy coincidence, the coagulation panel convenes tomorrow (Thursday) at 1100-1200. The roster is among the four that I have included with this email, and really is the "who's who" in the coagulation world. I will be on the call of course, and it occurs to me that you (plural) might want to join if able. I think it might give some insight into how those who are global experts and also in the front lines are seeing the hematology, the clinical realization, and where they think the best therapies might lie.

Let me know if you are interested. It will be a large call line and you can choose to identify yourselves or not.

If you want access to anyone on any of these panels, please let me know and I will be delighted to facilitate.

Tim

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Sent: Wednesday, April 29, 2020 8:59 AM
To: Koroshetz, Walter (NIH/NINDS) [E] <(b) (6)> ; Buchman, Tim (OS/ASPR/BARDA) (CTR) <(b) (6)>
Cc: Adam, Stacey (FNIH) [T] <(b) (6)> ; Hughes, Eric <(b) (6)>
Subject: FW: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions
Importance: High

Hi Walter and Tim,

I am joining you as a scorer for anticoagulants but am no expert! I'd like to see if we can take advantage on your knowledge and experience and ask if you think there should be other candidates on our list. If so, will you please share those amongst our scoring group so we can score them as well?

Thanks!

Sarah

From: Adam, Stacey (FNIH) [T] < (b) (6) >

Sent: Wednesday, April 29, 2020 8:34 AM

To: Eric Hughes < (b) (6) > Read, Sarah (NIH/NIAID) [E] < (b) (6) > Ruxandra Draghia-Akli < (b) (6) > Mellors, John W < (b) (6) > Naimish Patel < (b) (6) > Colvis, Christine (NIH/NCATS) [E] < (b) (6) > Young, John < (b) (6) > Stein, Peter (FDA/CDER) < (b) (6) > Poole, Mike < (b) (6) > Buchman, Tim (OS/ASPR/BARDA) (CTR) < (b) (6) > Vincent, Michael < (b) (6) > Wung, Peter /US < (b) (6) > Keith Gottesdiener < (b) (6) > Elliott Levy < (b) (6) > Koroshetz, Walter (NIH/NINDS) [E] < (b) (6) > Higgs, Elizabeth (NIH/NIAID) [E] < (b) (6) >
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Subject: Results of Wave 1 Triage, Wave 1 Agent Prioritization Score Sheet, and Directions

Importance: High

Dear TX-Clinical Agent Prioritization Subgroup,

Thank all once again for a very productive and educational discussion yesterday. We truly appreciate all the time and effort you are committing to this.

With our tie-breaker votes in (thanks Walter) and the discussion yesterday. I think we have the list for scoring down to a very manageable number, and as decided yesterday, we will breakup the list into agent subclasses and have just a subset of reviewers score each subclass that they personally feel they are well qualified to review: antivirals, host targeted/immune modulators, and symptomatic/supportive therapies. You all were kind enough to email me your choices so our group will be broken down into the following review groups:

Antivirals

Libby Higgs

John Young

Ruxandra Draghia-Akli

John Mellors

Host Targeted/Immune Modulators

Group 1

Eric Hughes

Naimish Patel

Elliott Levy

Group 2

Mike Vincent

Peter Wung

Keith Gottesdiener

Symptomatic/Supportive

Sarah Read

Walter Koroshetz

Tim Buchman

You will notice that the Host Targeted/Immune Modulators reviewers are broken into 2 groups. This is because they ended up with the largest number of agents and the broadest categories of mechanisms. Therefore, we are splitting the agents and the review group in half to allow them to complete a thorough review in the short timelines that we are

shooting for. You will see that the score sheet for the Host Targeted/Immune Modulators has also been split accordingly.

As described yesterday, in the attached spreadsheet you will find the final triage report with all the rationale from the original triage to the right of the "Keep/Drop" column. This may or may not be helpful in your reviews. I am also once again attaching the compiled data spreadsheet such as it is, knowing that it may be helpful to some and some may choose to do their own research. However, both this and the clinical trials report are attached for those who will find them useful.

For the instructions for scoring, these are simple.

1. Open the **ACTIV Prioritization Criteria-2nd Stage Scoring Sheet-Wave 1** and then find the appropriate tab for the group above that you have selected to score.
2. Review your compounds according to all criteria across the top of the sheet and the scoring rubric within the drop-down menus for each criteria. With one exception, if the availability of the compound is unknown to you, you may leave this criteria blank and we will work to figure this out after the highest ranking agents are selected.
3. Record your scores in the spreadsheet.
4. Return the spreadsheet to myself and Elizabeth Kim { (b) (6) } by 8 am, Friday, May 1, if at all possible. *(If you are going to miss this deadline, please let us know by Thursday evening so we can plan accordingly.)*
5. Elizabeth and I will then tally the scores and prepare the reports for our meeting on Friday afternoon for discussion and any adjudication necessary by the group.

As always, if you have any questions or need anything from us that we can help with, please do not hesitate to reach out. We will also have a meeting on Thursday afternoon to address any questions the group might have ahead of finalizing your score sheets. This will also allow our advisory members to weigh in on the lists, as well.

Thank you in advance for all your hard efforts!

Thanks,
Stacey

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